1/21/04 2:37 pm Notification Tracking Sheet

==========
Bp number: 04-015-12n
==========

App number: 2004-35XRAB
Received: 1/15/04
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/14/04
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

Begin movement: 2/13/04
End movement: 2/13/05
Begin release: 2/13/04
End release: 2/13/05
Acre: 10.00
CBI status: CBI

(b) (6), (b) (7)(C)

		Initial	Date
1.	[√] Assign Bp number and initial data entry	[ajd]	[1/22/04]
2.	[√] Review by biotechnologist	[AMH]*	[1/23/04]*
3.	[√] Letter of notification to State Fed-ex	[KLD]	[1/29/04]*
4.	[ ] State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR *	[ ]	[ ]
Interstate	*Dest*	MN	*	*NER *	[ ]	[ ]
Interstate	*Dest*	MO	*	*SCR *	[ ]	[ ]
Interstate	*Dest*	ND	*	*SCR *	[ ]	[ ]
Interstate	*Orig*	KS	*	*SCR *		
Interstate	*Orig*	MN	*	*NER *		
Interstate	*Orig*	MO	*	*SCR *		
Interstate	*Orig*	ND	*	*SCR *		
Release	*	*MN	*	1*NER *	[ ]	[ ]

5.	[√] Enter genes into database	[ajd]	[1/23/04]
6.	[√] Letter of acknowledgement/denial/withdraw	[KLD]	[3/17/04]*
7.	[√] Enter final data into database	[KLD]	[3/19/04]
8.	[ ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

6/3

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CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-35XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-12n

1. USDA Reference Number

2. Application Reference Number 2004-35XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 13, 2004 - February 13, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from cultivar Bobwhite

OR120018_BR_011094

Monsanto Reference ID
2004-35XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [redacted] (b) (4) [redacted] (b) (4) ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011095

Monsanto Reference ID
2004-35XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to ___10,000_ pounds of wheat seed to and from each location.

ORIGIN:

KS, MN, MO, ND

DESTINATION:

KS, MN, MO, ND

Ship From/Ship To:

KS

* [redacted] Riley County/Province, KS, [redacted] USA

CONTACT: [redacted] KS [redacted] USA [redacted]

]-CBI

* [redacted] Pottawattamie County/Province, KS [redacted] USA

CONTACT: [redacted] KS, [redacted] USA, [redacted]

]-CBI

MN

* [redacted] Marshall County/Province, MN [redacted] USA

CONTACT: [redacted] MN [redacted] USA, [redacted]

]-CBI

* [redacted] Polk County/Province, MN, [redacted] U.S.A.

OR120018_BR_011096

Monsanto Reference ID
2004-35XRAB

CONTACT: [redacted] MN, [redacted] USA, [redacted]

]-CBI

*[[redacted] Ramsey County/Province, MN, [redacted] USA

CONTACT [redacted] MN [redacted] USA [redacted]

]-CBI

MO

*[[redacted] St. Louis County/Province, MO, [redacted] USA

CONTACT [redacted] MO, [redacted] USA, [redacted]

]-CBI

ND

* [redacted] Cass County/Province, ND, [redacted] USA

CONTACT: [redacted] ND [redacted] USA, [redacted]

]-CBI

OR120018_BR_011097

Monsanto Reference ID
2004-35XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1)

MN

[(b) (4) Polk County/Province, MN, (b) (4) U.S.A., 10 acres. (2147301548)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

OR120018_BR_011098

MONSANTO imagine

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-35XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 14, 2008

OR120018_BR_011099

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S. , 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982). Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

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CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-35XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-12n

1. USDA Reference Number

2. Application Reference Number 2004-35XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 13, 2004 - February 13, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from cultivar Bobwhite

OR120018_BR_011103

Monsanto Reference ID
2004-35XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011104

CBI-DELETED

Monsanto Reference ID
2004-35XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to ___10,000_ pounds of wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
KS, MN, MO, ND	KS, MN, MO, ND

Ship From/Ship To:

KS

[CBI Deleted] -- *Riley County/Province, KS, USA

[CBI Deleted] -- *Pottawattamie County/Province, KS, USA

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

[CBI Deleted] -- *Polk County/Province, MN, U.S.A.

[CBI Deleted] -- *Ramsey County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

OR120018_BR_011105

CBI-DELETED

Monsanto Reference ID
2004-35XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1)

MN

[CBI Deleted] -- Polk County/Province, MN, U.S.A., 10 acres.

OR120018_BR_011106

MONSANTO
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CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-35XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 14, 2008

OR120018_BR_011107

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MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-35XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-12n

1. USDA Reference Number

2. Application Reference Number 2004-35XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

4. Duration of Introduction

Interstate Movement and Release February 13, 2004 - February 13, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from cultivar Bobwhite

OR120018_BR_011108

Monsanto Reference ID
2004-35XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4) *CBI*

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011109

Monsanto Reference ID
2004-35XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to ___10,000_ pounds of wheat seed to and from each location.

ORIGIN:

KS, MN, MO, ND

DESTINATION:

KS, MN, MO, ND

Ship From/Ship To:

KS

*[(b) (4)
Riley County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) Pottawattamie County/Province, KS, (b) (4)
USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

]-CBI

MN

*[(b) (4) Marshall County/Province, MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) Polk County/Province, MN, (b) (4)
U.S.A.

OR120018_BR_011110

Monsanto Reference ID
2004-35XRAB

CONTACT: [redacted] MN [redacted] USA [redacted]

]-CBI

*[[redacted] Ramsey County/Province, MN, [redacted] USA

CONTACT: [redacted] MN [redacted] USA [redacted]

]-CBI

MO

*[[redacted] St. Louis County/Province, MO, [redacted] USA

CONTACT [redacted] MO, [redacted] USA [redacted]

]-CBI

ND

*[[redacted] Cass County/Province, ND, [redacted] USA

CONTACT: [redacted] ND, [redacted] USA, [redacted]

]-CBI

OR120018_BR_011111

Monsanto Reference ID
2004-35XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1)

MN

[(b) (4) Polk County/Province, MN, (b) (4) U.S.A., 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

OR120018_BR_011112

MONSANTO
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MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-35XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 14, 2003

OR120018_BR_011113

Monsanto ID: 2004-35XRAB

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S. , 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982). Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO
imagine

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-35XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-12n

1. USDA Reference Number

2. Application Reference Number 2004-35XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Monsanto Company

Email (b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 13, 2004 - February 13, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from cultivar Bobwhite

OR120018_BR_011117

CBI-DELETED

Monsanto Reference ID
2004-35XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011118

Monsanto Reference ID
2004-35XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to ___10,000_ pounds of wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
KS, MN, MO, ND	KS, MN, MO, ND

Ship From/Ship To:

KS

[CBI Deleted] -- *Riley County/Province, KS, USA

[CBI Deleted] -- *Pottawattamie County/Province, KS, USA

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

[CBI Deleted] -- *Polk County/Province, MN, U.S.A.

[CBI Deleted] -- *Ramsey County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

OR120018_BR_011119

CBI-DELETED

Monsanto Reference ID
2004-35XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1)

MN

[CBI Deleted] -- Polk County/Province, MN, U.S.A., 10 acres.

OR120018_BR_011120

MONSANTO
imagine

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-35XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 14, 2004

OR120018_BR_011121

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 21, 2004

Dear Mr. Sim IV:

Enclosed is notification 04-015-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-12n	Applicant #:	2004-35XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat

Interstate destination: KS MN MO ND
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011122

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 21, 2004

Dear Dr. Hanks:

Enclosed is notification 04-015-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-12n Applicant #: 2004-35XRAB
Received: January 15, 2004 Effective: February 14, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO ND
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011123

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 21, 2004

Dear Mr. Brown:

Enclosed is notification 04-015-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-12n	Applicant #:	2004-35XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat

Interstate destination: KS MN MO ND
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011124

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 21, 2004

Dear Mr. Nelson:

Enclosed is notification 04-015-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-12n Applicant #: 2004-35XRAB
Received: January 15, 2004 Effective: February 14, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO ND
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011125

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 21, 2004

Dear Dr. Hanks:

Enclosed is notification 04-015-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-12n Applicant #: 2004-35XRAB
Received: January 15, 2004 Effective: February 14, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO ND
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. with the attached additional condition

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 2-20-04

State: MN

Rptloc01/R4

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FEB 20 2004

OR120018_BR_011126

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 21, 2004

Dear Mr. Nelson:

Enclosed is notification 04-015-12n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-12n	Applicant #:	2004-35XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat

Interstate destination: KS MN MO ND
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State Official: David R Nelson

Signature: (b) (6), (b) (7)(C)

Date: 4-16-04

State: ND

Rptloc01/R4

MAR 16 2004

OR120018_BR_011127

MAR.16.2004 7:39PM NO.801 P.2

March 17, 2004

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after March 17, 2004.**

Interstate movement and Release
Notification no. 04-015-12n (2004-35XRAB)
Regulated article - Wheat
Destinations - Kansas, Minnesota, Missouri, North Dakota

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Minnesota has (attached) additional conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
File number 04-015-12n

OR120018_BR_011128

MINNESOTA DEPARTMENT OF AGRICULTURE
FROM THE FARM TO YOUR FAMILY

(651) 296-1277

February 20, 2004

Ms. Mary Jackson
Biotechnology Program Operations - Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

RE: Additional Conditions for Release of Wheat 04-015-12n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain must be at least 100 feet.
3. Because of the possibility of volunteers:
   - If trials are harvested by hand or with small plot equipment, wheat, or crops that would make locating or controlling volunteer wheat difficult (i.e. other small grains), should not be grown within the field trial area nor within a 33 feet isolation area around the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
   - If trials are harvested by commercial combine rather than by small plot combine, an additional 150 feet isolation area around the field trial area during the subsequent two (2) growing seasons is required.
4. Consultation should occur with the Minnesota Research and Outreach Center Directors at the release sites prior to planting to assure that isolation of at least 330 feet from foundation seedstock production and other significant plantings is maintained.

These conditions are in addition to those contained in the applicant's "Wheat Field Release Performance Standards" dated January 2004.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.
State Biotechnologist

OR120018_BR_011129

Confirmation Report–Memory Send

Time : Mar-19-04 09:58am
Tel line 1 :
Tel line 2 :
Name :

Job number : 669

Date : Mar-19 09:56am

To : 916367377085

Document Pages : 02

Start time : Mar-19 09:57am

End time : Mar-19 09:58am

Pages sent : 02

Job number : 669 *** SEND SUCCESSFUL ***

USDA United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

March 17, 2004

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 17, 2004.

Interstate movement and Release
Notification no. 04-015-12n (2004-35XRAB)
Regulated article - Wheat
Destinations - Kansas, Minnesota, Missouri, North Dakota

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Minnesota has (attached) additional conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND

APHIS- Protecting American Agriculture

An Equal Opportunity Employer

OR120018_BR_011130

No CBI

2004 Wheat Field Test Report
USDA #04-015-12n Monsanto #2004-35XRAB

March 9, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
2147301548	Polk	MN	Not Planted

OR120018_BR_011131

Omm 3/11/05

1/21/04 2:37 pm Notification Tracking Sheet

==========
Bp number: 04-015-13n
==========

App number: 2004-39XRAB
Received: 1/15/04
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/14/04
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person: (b) (6), (b) (7)(C)
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

Begin movement: 2/13/04
End movement: 2/13/05
Begin release: 2/13/04
End release: 2/13/05
Acre: 20.00
CBI status: CBI

		Initial	Date
1.	[✓] Assign Bp number and initial data entry	[aid]	[1/22/04
2.	[✓] Review by biotechnologist	[YMH]*	[1/23/04]*
3.	[✓] Letter of notification to State Fed-ex	[KLQ]	[1/29/04]*
4.	[ ] State response		

	O/d	Loc	Site Reg		
Interstate	*Dest*	KS	*SCR*	[ ]	[ ]
Interstate	*Dest*	MN	*NER*	[ ]	[ ]
Interstate	*Dest*	MO	*SCR*	[ ]	[ ]
Interstate	*Dest*	MT	*WR*	[ ]	[ ]
Interstate	*Dest*	ND	*SCR*	[ ]	[ ]
Interstate	*Orig*	KS	*SCR*		
Interstate	*Orig*	MN	*NER*		
Interstate	*Orig*	MO	*SCR*		
Interstate	*Orig*	MT	*WR*		
Interstate	*Orig*	ND	*SCR*		
Release	*	ND	2*SCR*	[ ]	[ ]

5.	[✓] Enter genes into database	[aid]	[1/23/04
6.	[✓] Letter of acknowledgement/denial/withdraw	[KLQ]	[3/17/04]*
7.	[✓] Enter final data into database	[KLQ]	[3/19/04]
8.	[ ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

7/3

MONSANTO imagine

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-39XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037 04-015-13n

1. USDA Reference Number

2. Application Reference Number 2004-39XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C) @monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 13, 2004 - February 13, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from the cultivar Bobwhite

OR120018_BR_011133

Monsanto Reference ID
2004-39XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [redacted] (b) (4) [redacted] (b) (4) ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011134

Monsanto Reference ID
2004-39XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to __10,000__ pounds of wheat seed to and from each location.

ORIGIN:

KS, MN, MO, MT, ND

DESTINATION:

KS, MN, MO, MT, ND

Ship From/Ship To:

KS

* (b) (4)
Riley County/Province, KS (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) Pottawattamie County/Province, KS, (b) (4)
USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

]-CBI

MN

* (b) (4) Marshall County/Province, MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

]-CBI

MO

* (b) (4) St. Louis County/Province, MO,

OR120018_BR_011135

Monsanto Reference ID
2004-39XRAB

(b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

MT

* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

ND

*[(b) (4) Mountrail County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) Burke County/Province, ND, (b) (4), USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C), U.S.A., (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) Burke County/Province, ND, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

]-CBI

OR120018_BR_011136

Monsanto Reference ID
2004-39XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(2)

ND

[(b) (4), (b) (6), (b) (7)(C) Mountrail County/Province, ND, (b) (4), (b) (6), (b) USA, 10 acres. (b) (4), (b) (6), (b) (7)(C)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) U.S.A. (b) (4), (b) (6), (b) (7)(C)

]-CBI

[(b) (4) Burke County/Province, ND, (b) (4) USA, 10 acres. (b) (4)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) U.S.A., (b) (4), (b) (6), (b) (7)(C)

]-CBI

OR120018_BR_011137

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-39XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 14, 2004

OR120018_BR_011138

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S. , 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982). Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011139

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

OR120018_BR_011141

MONSANTO imagine

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-39XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-13n

1. USDA Reference Number

2. Application Reference Number 2004-39XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Monsanto Company

Email (b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 13, 2004 - February 13, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from the cultivar Bobwhite

OR120018_BR_011142

Monsanto Reference ID
2004-39XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011143

Monsanto Reference ID
2004-39XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to __10,000__ pounds of wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
KS, MN, MO, MT, ND	KS, MN, MO, MT, ND

Ship From/Ship To:

KS

[CBI Deleted] -- *Riley County/Province, KS, USA

[CBI Deleted] -- *Pottawattamie County/Province, KS, USA

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

ND

[CBI Deleted] -- *Mountrail County/Province, ND, USA

[CBI Deleted] -- *Burke County/Province, ND, USA

[CBI Deleted] -- *Burke County/Province, ND, U.S.A.

OR120018_BR_011144

Monsanto Reference ID
2004-39XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(2)

ND

[CBI Deleted] -- Mountrail County/Province, ND, USA, 10 acres.

[CBI Deleted] -- Burke County/Province, ND, USA, 10 acres.

OR120018_BR_011145

MONSANTO imagine

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-39XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 14, 2004

OR120018_BR_011146

MONSANTO
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CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-39XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-13n

1. USDA Reference Number

2. Application Reference Number 2004-39XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 13, 2004 - February 13, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from the cultivar Bobwhite

OR120018_BR_011147

Monsanto Reference ID
2004-39XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] *CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011148

Monsanto Reference ID
2004-39XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to __10,000__ pounds of wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
KS, MN, MO, MT, ND	KS, MN, MO, MT, ND

Ship From/Ship To:

KS

[CBI Deleted] -- *Riley County/Province, KS, USA

[CBI Deleted] -- *Pottawattamie County/Province, KS, USA

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

ND

[CBI Deleted] -- *Mountrail County/Province, ND, USA

[CBI Deleted] -- *Burke County/Province, ND, USA

[CBI Deleted] -- *Burke County/Province, ND, U.S.A.

OR120018_BR_011149

CBI-DELETED

Monsanto Reference ID
2004-39XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(2)

ND

[CBI Deleted] -- Mountrail County/Province, ND, USA, 10 acres.

[CBI Deleted] -- Burke County/Province, ND, USA, 10 acres.

OR120018_BR_011150

MONSANTO
imagine

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-39XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 14, 2004

OR120018_BR_011151

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 21, 2004

Dear Mr. Sim IV:

Enclosed is notification 04-015-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-13n	Applicant #:	2004-39XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat

Interstate destination: KS MN MO MT ND
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011152

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 21, 2004

Dear Dr. Hanks:

Enclosed is notification 04-015-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-13n Applicant #: 2004-39XRAB
Received: January 15, 2004 Effective: February 14, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO MT ND
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011153

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 21, 2004

Dear Mr. Brown:

Enclosed is notification 04-015-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-13n Applicant #: 2004-39XRAB
Received: January 15, 2004 Effective: February 14, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO MT ND
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011154

file copy

Ms. Lori Witham
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 21, 2004

Dear Ms. Witham:

Enclosed is notification 04-015-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-13n Applicant #: 2004-39XRAB
Received: January 15, 2004 Effective: February 14, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO MT ND
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011155

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 21, 2004

Dear Mr. Nelson:

Enclosed is notification 04-015-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-13n Applicant #: 2004-39XRAB
Received: January 15, 2004 Effective: February 14, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO MT ND
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011156

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 21, 2004

Dear Dr. Hanks:

Enclosed is notification 04-015-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-13n
Received: January 15, 2004
Institution: Monsanto
Interstate destination: KS MN MO MT ND
Release destination: ND
Applicant #: 2004-39XRAB
Effective: February 14, 2004
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. movement only

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 2-6-04

State: MN

Rptloc01/R4

FEB 6 2004

OR120018_BR_011157

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Ms. Lori Witham
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

January 21, 2004

Dear Ms. Witham:

Enclosed is notification 04-015-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-13n Applicant #: 2004-39XRAB
Received: January 15, 2004 Effective: February 14, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO MT ND
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

✓ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature: (b) (6), (b) (7)(C)

Date: 2/2/04

State: Montana

Rptloc01/R4

FEB 2 2004

OR120018_BR_011158

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 21, 2004

Dear Mr. Nelson:

Enclosed is notification 04-015-13n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-13n	Applicant #:	2004-39XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat

Interstate destination: KS MN MO MT ND
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

____ State concurs with APHIS determination.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R Nelson

Signature: (b) (6), (b) (7)(C)

Date: 3-16-04

State: ND

Rptloc01/R4

MAR 17 2004

OR120018_BR_011159

March 17, 2004

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after March 17, 2004.**

Interstate movement and Release
Notification no. 04-015-13n (2004-39XRAB)
Regulated article - Wheat
Destinations - Kansas, Minnesota, Missouri, Montana, North Dakota

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of North Dakota has (attached) supplemental conditions.

In addition, the State of Minnesota concur for movement only.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
L. Witham, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
File number 04-015-13n

OR120018_BR_011160

AGRICULTURE COMMISSIONER
ROGER JOHNSON

PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: Mary Jackson
Biotechnology Program Operations – Permit Unit
USDA APHIS
4700 River Road
Riverdale MD 27037

FROM: David R. Nelson (b) (6), (b) (7)(C)
DATE: March 16, 2004
RE: Supplemental Conditions for Release of Wheat

Bp Number	Applicant Number	Institution
04-015-13n	2004-39XRAB	Monsanto
04-021-05n	2004-36XRAB	Monsanto
04-035-06n	2004-225XRAB	Monsanto
04-062-02n	2004-363XRAB	Monsanto
04-064-07n	2004-375XRAB	Monsanto
04-063-04n	SYN2004-107	Syngenta

The North Dakota Department of Agriculture concurs with the above mentioned notifications for transgenic wheat and suggests the following supplemental conditions. Thank you for the opportunity to comment.

North Dakota Supplemental Conditions 2004

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.

2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.

3. Because of the possibility of volunteers:

   - Wheat, or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.

   - If a transgenic wheat plot is harvested with a commercial combine (other than a small plot combine), then wheat or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown with the field trial area nor within 50 meters of the field trial area during the subsequent two growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.

- Consultation should occur with the North Dakota Agriculture Experiment Station Director and the NDSU Seedstocks Director prior to planting to assure that isolation of at least 330 feet from Foundation Seedstock production and other significant ND Agricultural Experiment Station plantings is maintained.

CONFIDENTIAL

2004 Wheat Field Test Report
USDA #04-015-13n Monsanto #2004-39XRAB

March 24, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
2147318001	Mountrail	ND	
2147307368	Burke	ND	Not Planted

Mountrail County/ND (2147318001)

Planting Date: 04/30/2004

Destruct Date: 05/27/2004

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4) (b) (4) - CBI

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4) (b) (4) - CBI

OR120018_BR_011162

3/25/05

Monsanto ID: 2004-39XRAB

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943#44 (lOth Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011163

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

OR120018_BR_011164

CBI-DELETED

2004 Wheat Field Test Report
USDA #04-015-13n Monsanto #2004-39XRAB

March 24, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
2147318001	Mountrail	ND	
2147307368	Burke	ND	Not Planted

Mountrail County/ND (2147318001)

Planting Date: 04/30/2004

Destruct Date: 05/27/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

OR120018_BR_011165

1/21/04 2:37 pm Notification Tracking Sheet

==========
Bp number: 04-015-14n
==========

App number: 2004-40XRAB
Received: 1/15/04
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/14/04
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

Begin movement: 2/13/04
End movement: 2/13/05
Begin release: 2/13/04
End release: 2/13/05
Acre: 20.00
CBI status: CBI

		Initial	Date
1.	[✓] Assign Bp number and initial data entry	[ajd]	[1/22/04
2.	[✓] Review by biotechnologist	[mw]*	[1/23/04]*
3.	[✓] Letter of notification to State Fed-ex	[KLO]	[1/28/04]*
4.	[ ] State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR *	[ ]	[ ]
Interstate	*Dest*	MN	*	*NER *	[ ]	[ ]
Interstate	*Dest*	MO	*	*SCR *	[ ]	[ ]
Interstate	*Dest*	SD	*	*SCR *	[ ]	[ ]
Interstate	*Orig*	KS	*	*SCR *		
Interstate	*Orig*	MN	*	*NER *		
Interstate	*Orig*	MO	*	*SCR *		
Interstate	*Orig*	SD	*	*SCR *		
Release	*	*SD	*	2*SCR *	[ ]	[ ]

5.	[✓] Enter genes into database	[ajd]	[1/23/04
6.	[✓] Letter of acknowledgement/denial/withdraw	[KLO]	[2/9/04]*
7.	[✓] Enter final data into database	[KLO]	[2/9/04]
8.	[ ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

MONSANTO imagine

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-40XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

January 14, 2004

04-015-14n

1. USDA Reference Number

2. Application Reference Number 2004-40XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Monsanto Company

Email (b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 13, 2004 - February 13, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from the cultivar Bobwhite

OR120018_BR_011167

Monsanto Reference ID
2004-40XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [redacted] (b) (4) [redacted] (b) (4) ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011168

Monsanto Reference ID
2004-40XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to _10,000__ pounds of wheat seed to and from each location.

ORIGIN:

KS, MN, MO, SD

DESTINATION:

KS, MN, MO, SD

Ship From/Ship To:

KS

* (b) (4)
Riley County/Province, KS, (b) (4) USA

CONTACT (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) KS (b) (6), (b) (7)(C), (b) (4) USA (b) (6), (b) (7)(C), (b) (4)

]-CBI

* (b) (4) Pottawattamie County/Province, KS, (b) (4)
USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) KS, (b) (6), (b) (7)(C), USA,
(b) (6), (b) (7)(C), (b) (4)

]-CBI

MN

* (b) (4) Marshall County/Province, MN, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) MN, (b) (6), (b) (7)(C), USA,
(b) (6), (b) (7)(C), (b) (4)

]-CBI

MO

* (b) (4) St. Louis County/Province, MO,

OR120018_BR_011169

Monsanto Reference ID
2004-40XRAB

(b) (4) USA

CONTACT (b) (6), (b) (7)(C), (b) (4) MO, (b) (6), (b) (7)(C), (b) (4) USA, (b) (6), (b) (7)(C), (b) (4)

]-CBI

SD

* (b) (6), (b) (7)(C), (b) (4), Spink County/Province, SD (b) (6), (b) (7)(C), (b) USA

CONTACT (b) (6), (b) (7)(C), (b) (4) SD, (b) (6), (b) (7)(C), (b) USA, (b) (6), (b) (7)(C), (b) (4)

]-CBI

* (b) (4) Brown County/Province, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) SD, (b) (6), (b) (7)(C), (b) USA, (b) (6), (b) (7)(C), (b) (4)

]-CBI

* (b) (4) Minnehaha County/Province, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) SD, (b) (6), (b) (7)(C), (b) USA, (b) (6), (b) (7)(C), (b) (4)

]-CBI

* (b) (4), Brookings County/Province, SD, (b) (4) USA

CONTACT (b) (6), (b) (7)(C), (b) (4) SD, (b) (6), (b) (7)(C), (b) USA, (b) (6), (b) (7)(C), (b) (4)

]-CBI

* (b) (4) Codington County/Province, SD, (b) (4) USA

CONTACT: (b) (6), (b) (7)(C), (b) (4) SD, (b) (6), (b) (7)(C), (b) USA, (b) (6), (b) (7)(C), (b) (4)

]-CBI

OR120018_BR_011170

Monsanto Reference ID
2004-40XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD(2)

SD

[(b) (6), (b) (7)(C), (b) (4) Spink County/Province, SD, [redacted] USA, 10 acres. (2147308028)

RESPONSIBLE PERSON/RESEARCHER (b) (6), (b) (7)(C), (b) (4)
[redacted] SD, [redacted] USA, [redacted]

]-CBI

[(b) (4), Codington County/Province, SD (b) (4) USA, 10 acres. (2147303325)

RESPONSIBLE PERSON/RESEARCHER: (b) (6), (b) (7)(C), (b) (4)
[redacted] SD, [redacted] USA, [redacted]

]-CBI

OR120018_BR_011171

MONSANTO
imagine

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-40XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 14, 2004

OR120018_BR_011172

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S. , 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982). Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO imagine

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-40XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

January 14, 2004

04-015-14n

1. USDA Reference Number

2. Application Reference Number 2004-40XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 13, 2004 - February 13, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from the cultivar Bobwhite

OR120018_BR_011176

CBI-DELETED

Monsanto Reference ID
2004-40XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011177

Monsanto Reference ID
2004-40XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to _10,000__ pounds of wheat seed to and from each location.

ORIGIN:

KS, MN, MO, SD

DESTINATION:

KS, MN, MO, SD

Ship From/Ship To:

KS

[CBI Deleted] -- *Riley County/Province, KS, USA

[CBI Deleted] -- *Pottawattamie County/Province, KS, USA

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

SD

[CBI Deleted] -- *Spink County/Province, SD, USA

[CBI Deleted] -- *Brown County/Province, SD, USA

[CBI Deleted] -- *Minnehaha County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, USA

[CBI Deleted] -- *Codington County/Province, SD, USA

OR120018_BR_011178

CBI-DELETED

Monsanto Reference ID
2004-40XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD(2)

SD

[CBI Deleted] -- Spink County/Province, SD, USA, 10 acres.

[CBI Deleted] -- Codington County/Province, SD, USA, 10 acres.

OR120018_BR_011179

MONSANTO
imagine

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-40XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 14, 2004

OR120018_BR_011180

MONSANTO
imagine

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-40XRAB

Permit Unit

January 14, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-015-14n

1. USDA Reference Number

2. Application Reference Number 2004-40XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Monsanto Company

Email (b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 13, 2004 - February 13, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from the cultivar Bobwhite

OR120018_BR_011181

CBI-DELETED

Monsanto Reference ID
2004-40XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted]

CBI

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011182

Monsanto Reference ID
2004-40XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to _10,000__ pounds of wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
KS, MN, MO, SD	KS, MN, MO, SD

Ship From/Ship To:

KS

[CBI Deleted] -- *Riley County/Province, KS, USA

[CBI Deleted] -- *Pottawattamie County/Province, KS, USA

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

SD

[CBI Deleted] -- *Spink County/Province, SD, USA

[CBI Deleted] -- *Brown County/Province, SD, USA

[CBI Deleted] -- *Minnehaha County/Province, SD, USA

[CBI Deleted] -- *Brookings County/Province, SD, USA

[CBI Deleted] -- *Codington County/Province, SD, USA

OR120018_BR_011183

CBI-DELETED

Monsanto Reference ID
2004-40XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

SD(2)

SD

[CBI Deleted] -- Spink County/Province, SD, USA, 10 acres.

[CBI Deleted] -- Codington County/Province, SD, USA, 10 acres.

OR120018_BR_011184

MONSANTO imagine

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-40XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 14, 2004

OR120018_BR_011185

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 21, 2004

Dear Mr. Sim IV:

Enclosed is notification 04-015-14n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-14n Applicant #: 2004-40XRAB
Received: January 15, 2004 Effective: February 14, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO SD
Release destination: SD

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011186

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 21, 2004

Dear Dr. Hanks:

Enclosed is notification 04-015-14n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-14n Applicant #: 2004-40XRAB
Received: January 15, 2004 Effective: February 14, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO SD
Release destination: SD

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011187

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 21, 2004

Dear Mr. Brown:

Enclosed is notification 04-015-14n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-14n Applicant #: 2004-40XRAB
Received: January 15, 2004 Effective: February 14, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO SD
Release destination: SD

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011188

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

January 21, 2004

Dear Mr. Fridley:

Enclosed is notification 04-015-14n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-14n Applicant #: 2004-40XRAB
Received: January 15, 2004 Effective: February 14, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO SD
Release destination: SD

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011189

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 21, 2004

Dear Dr. Hanks:

Enclosed is notification 04-015-14n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-015-14n	Applicant #:	2004-40XRAB
Received:	January 15, 2004	Effective:	February 14, 2004
Institution:	Monsanto	Recipient:	Wheat

Interstate destination: KS MN MO SD
Release destination: SD

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. Statement only

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 2-6-04

State: MN

Rptloc01/R4

FEB 6 2004

OR120018_BR_011190

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

January 21, 2004

Dear Mr. Fridley:

Enclosed is notification 04-015-14n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-015-14n
Received: January 15, 2004
Institution: Monsanto
Interstate destination: KS MN MO SD
Release destination: SD
Applicant #: 2004-40XRAB
Effective: February 14, 2004
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

JAN 2004 RECEIVED S. D. DEPT. OF AGRICULTURE

STATE RESPONSE TO NOTIFICATION

__X__ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 1/29/04

State: South Dakota

Rptloc01/R4

JAN 30 2004

OR120018_BR_011191

February 9, 2004

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Parkway W.
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after February 14, 2004.**

Interstate movement and Release
Notification no. 04-015-14n (2004-40XRAB)
Regulated article - Wheat
Destinations - Kansas, Minnesota, Missouri, South Dakota

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 04-015-14n

OR120018_BR_011192

MONSANTO

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

April 2, 2004

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the Site Responsible Researcher (SRR) name and/or contact information for the approved notification(s):

USDA#	Monsanto#
04-015-14n	2004-40XRAB

The release site(s):
(b) (6), (b) (7)(C), (b) (4) SD, - **CBI**

The former SRR/contact information is:
(b) (6), (b) (7)(C), (b) (4) SD (b) (6), (b) (7)(C), (b) (4) - **CBI**

The new SRR/contact information is:
(b) (6), (b) (7)(C), (b) (4) SD, - **CBI**

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

cc:
Ralph Stoaks

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

April 2, 2004

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the Site Responsible Researcher (SRR) name and/or contact information for the approved notification(s):

USDA#	**Monsanto#**
04-015-14n	2004-40XRAB

The release site(s):
[CBI Deleted] - Spink,SD

The former SRR/contact information is:
[CBI Deleted] - Brown, SD

The new SRR/contact information is:
[CBI Deleted] - Minnehaha, SD

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

David DeBoer
Compliance Specialist

cc:
Ralph Stoaks

NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed, this is an Internal PPQ Document

8/30/04

AHPIS Notification Number: 04-015-14n Crop: wheat

Applicant's Name: David DeBoer Trait/Gene: HT - glphosate

Name of Company & Cooperator at site: Monsanto - (b) (6), (b) (7)(C), (b) (4) Phone: (b) (6), (b) (7)(C), (b) (4)

Location of site: Codington Co Date of Inspection: _____

Type of location: ☐ Farm ☐ Nursery ☒ Other (describe) research farm

GPS/ GIS Coordinates (if available): Latitude _____ Longitude _____

Provide the answers below. Check "Y" for Yes and "N" for No. If the answer to any questions is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

I. Shipping, Maintenance at Destination, and Identification

A. Did all aspects of field trail maintain identity (seed storage, planting & harvest site, borders, field cages, etc.)? Y☒ N☐

B. Was a site map obtained or drawn by your for reference later (For harvest, flower removal, volunteers, etc.)? Y☐ N☒

– crop was planted and destroyed prior to inspection per Monsanto

II. Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants

A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? Y☒ N☐

B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located within the pollination distance for the plants? Y☒ N☐

C. Which of the five containment options is the applicant using? Check one of the options below. If none, please note it here and state this in your cover letter to the Regional Program Manager. _____

1. Removing Flowers _____

Is there any evidence that the plants have flowers or that flowers have been removed? Y☐ N☐

2. Bagging Flowers/Tassels _____

Does the applicant have material to bag reproductive structures? Y☐ N☐

3. Terminating the experiment before flowering _____

Were plants destroyed or removed from the field before any flowers were allowed to release pollen? Y☐ N☐

4. Physical Isolation _____

If there are any non-transgenic compatible plants within the distance stated in Table 1 (for pollination distance), were they being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenic? Y☒ N☐

5. Temporal Isolation _____

Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? Y☐ N☐

OR120018_BR_011195

D. If the applicant's design standards use border rows, are there the stated numbers of border rows? Y☐ n/a N☐

E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic? Y☐ n/a N☐

Plants of the same species? Y☐ n/a N☐

F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards? Y☐ n/a N☐

G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards? Y☒ N☐

H. Was the field site marked as stated in the design standards? Y☐ N☐

I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts? Y☒ N☐

J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive? Y☒ N☐

III. Devitalization

A. Does the applicant have the necessary equipment to devitalize the plant material as described? Y☒ N☐

In the design standards (e.g., an autoclave, steamer, burial pit, incineration)? Y☒ N☐

B. Remind applicant that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed and approved.

The signed original of this report was furnished to Juan Roman, APHIS, BRS Y☒ N☐

Inspecting Officer Signature: (b) (6), (b) (7)(C)

Printed Name: Amy Mehman

Phone: 605 224 1713 Location of PPQ Officer: Pierre SD

Names and Affiliation of Any Other Persons at the inspection:

Please fax/ email completed worksheet to:	*Please FedEx original worksheet to:*
Ralph Stoaks, Regional Biotechnologist	*Juan Roman, Chief Biotechnology Program Operations*
2150 Centre Ave. Bldg. B, 3E10	*4700 River Road, Unit 147, 5B53*
Ft. Collins, CO 80526	*Riverdale, MD 20737*
Phone: 970-494-7573 Fax: 970-494-7576	*Phone: 301-734-0029*
Email: ralph.d.stoaks@aphis.usda.gov	

Revised
3/11/04

CONFIDENTIAL

2004 Wheat Field Test Report
USDA #04-015-14n Monsanto #2004-40XRAB

May 17, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State
2147308028	Spink	SD
2147303325	Codington	SD

Spink County/SD (2147308028)

Planting Date: 04/27/2004

Destruct Date: 05/26/2004

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4) - CBI

Field Monitoring Observations for Disease Susceptibility: (b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

OR120018_BR_011197

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4) (b) (4) CBI

Codington County/SD (2147303325)

Planting Date: 04/12/2004

Destruct Date: 06/28/2004

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4) (b) (4) CBI

Field Monitoring Observations for Disease Susceptibility: (b) (4) (b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4) (b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4) (b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4) (b) (4)

Field Monitoring Observations for Plant Stand: (b) (4) (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4) (b) (4)

Additional Comments: (b) (4) - CBI

OR120018_BR_011198

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943#44 (lOth Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011199

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

OR120018_BR_011200

CBI-DELETED

2004 Wheat Field Test Report
USDA #04-015-14n Monsanto #2004-40XRAB

May 17, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State
2147308028	Spink	SD
2147303325	Codington	SD

Spink County/SD (2147308028)

Planting Date: 04/27/2004

Destruct Date: 05/26/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Codington County/SD (2147303325)

Planting Date: 04/12/2004

Destruct Date: 06/28/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

OR120018_BR_011201

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

OR120018_BR_011202

1/21/04 2:37 pm Notification Tracking Sheet

==========
Bp number: 04-021-05n
==========

App number: 2004-36XRAB
Received: 1/21/04
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 2/20/04
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

Begin movement: 2/19/04
End movement: 2/19/05
Begin release: 2/19/04
End release: 2/19/05
Acre: 60.00
CBI status: CBI

		Initial	Date
1.	[√] Assign Bp number and initial data entry	[ajd]	[1/22/04
2.	[√] Review by biotechnologist	[MJW]*	[1/23/04]*
3.	[√] Letter of notification to State Fed-ex	[KLN]	[1/28/04]*
4.	[ ] State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	KS	*	*SCR *	[ ]	[ ]
Interstate	*Dest*	MN	*	*NER *	[ ]	[ ]
Interstate	*Dest*	MO	*	*SCR *	[ ]	[ ]
Interstate	*Dest*	ND	*	*SCR *	[ ]	[ ]
Interstate	*Orig*	KS	*	*SCR *		
Interstate	*Orig*	MN	*	*NER *		
Interstate	*Orig*	MO	*	*SCR *		
Interstate	*Orig*	ND	*	*SCR *		
Release	*	ND	*	6*SCR *	[ ]	[ ]

5.	[√] Enter genes into database	[ajd]	[1/23/04
6.	[√] Letter of acknowledgement/denial/withdraw	[KLN]	[3/17/04]*
7.	[√] Enter final data into database	[KLN]	[3/19/04]
8.	[ ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

6/3

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MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-36XRAB

Permit Unit

January 20, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-021-05n

1. USDA Reference Number

2. Application Reference Number 2004-36XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 19, 2004 - February 19, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from the cultivar Bobwhite

OR120018_BR_011204

Monsanto Reference ID
2004-36XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [redacted] (b) (4) [redacted] (b) (4) *CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011205

Monsanto Reference ID
2004-36XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 Ship up to __10,000_____pounds wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
KS, MN, MO, ND	KS, MN, MO, ND

Ship From/Ship To:

KS

*[(b) (4)
Riley County/Province, KS (b) (4), USA

CONTACT (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) Pottawattamie County/Province, KS, (b) (4)
USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

]-CBI

MN

*[(b) (4) Marshall County/Province, MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA,
(b) (4), (b) (6), (b) (7)(C)

]-CBI

MO

*[(b) (4) St. Louis County/Province, MO,

OR120018_BR_011206

Monsanto Reference ID
2004-36XRAB

(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

ND

*[(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, (b) (4), (b) (6), (b) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) Fargo, ND, (b) (4), (b) (6), (b) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND (b) (4), (b) (6), (b) (7) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) Cass County/Province, ND (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) Foster County/Province, ND, (b) (4) U.S.A.

CONTACT (b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7) U.S.A., (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) Cass County/Province, ND (b) (4) U.S.A

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) U.S.A (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) Cass County/Province, ND, (b) (4)

OR120018_BR_011207

Monsanto Reference ID
2004-36XRAB

USA

CONTACT: [redacted] ND, [redacted] U.S.A [redacted]

]-CBI

*[redacted] Cass County/Province, ND, [redacted] USA

CONTACT [redacted] ND, [redacted] U.S.A, [redacted]

]-CBI

*[redacted] Cavalier County/Province, ND, [redacted] USA

CONTACT [redacted] ND [redacted] USA [redacted]

]-CBI

OR120018_BR_011208

Monsanto Reference ID
2004-36XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(6)

ND

(b) (4), (b) (6), (b) (7)(C) Cass County/Province, ND, [redacted] USA, 10 acres. (2147307361)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ND, [redacted] USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

[(b) (4), (b) (6), (b) (7)(C) , Cass County/Province, ND, [redacted] USA, 10 acres. (2147314745)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ND, [redacted] USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

(b) (4) , Foster County/Province, ND, (b) (4) U.S.A., 10 acres. (1611677957)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ND [redacted] U.S.A., (b) (4), (b) (6), (b) (7)(C)

]-CBI

[(b) (4) , Cass County/Province, ND, (b) (4) USA, 10 acres. (2147307378)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ND [redacted] U.S.A, (b) (4), (b) (6), (b) (7)(C)

]-CBI

(b) (4) Cass County/Province, ND, (b) (4) USA, 10 acres. (2147303287)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ND [redacted] U.S.A, (b) (4), (b) (6), (b) (7)(C)

]-CBI

OR120018_BR_011209

Monsanto Reference ID
2004-36XRAB

[redacted] Cavalier County/Province, ND [redacted] USA, 10 acres. (2147307343)

RESPONSIBLE PERSON/RESEARCHER [redacted] ND [redacted] USA, [redacted]

]-CBI

OR120018_BR_011210

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-36XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 20, 2004

OR120018_BR_011211

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S. , 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982). Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO
imagine
CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-36XRAB

Permit Unit

January 20, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-021-05n

1. USDA Reference Number

2. Application Reference Number 2004-36XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 19, 2004 - February 19, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from the cultivar Bobwhite

OR120018_BR_011215

Monsanto Reference ID
2004-36XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011216

Monsanto Reference ID
2004-36XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 Ship up to __10,000_____pounds wheat seed to and from each location.

ORIGIN:

KS, MN, MO, ND

DESTINATION:

KS, MN, MO, ND

Ship From/Ship To:

KS

[CBI Deleted] -- *Riley County/Province, KS, USA

[CBI Deleted] -- *Pottawattamie County/Province, KS, USA

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Foster County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, U.S.A

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cavalier County/Province, ND, USA

OR120018_BR_011217

CBI-DELETED

Monsanto Reference ID
2004-36XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(6)

ND

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.

[CBI Deleted] -- Foster County/Province, ND, U.S.A., 10 acres.

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.

[CBI Deleted] -- Cavalier County/Province, ND, USA, 10 acres.

OR120018_BR_011218

MONSANTO
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CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-36XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 20, 2004

OR120018_BR_011219

MONSANTO
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MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-36XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

January 20, 2004

04-021-05n

1. USDA Reference Number

2. Application Reference Number 2004-36XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release February 19, 2004 - February 19, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): lines derived from the cultivar Bobwhite

OR120018_BR_011220

Monsanto Reference ID
2004-36XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011221

CBI-DELETED

Monsanto Reference ID
2004-36XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 Ship up to __10,000_____pounds wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
KS, MN, MO, ND	KS, MN, MO, ND

Ship From/Ship To:

KS

[CBI Deleted] -- *Riley County/Province, KS, USA

[CBI Deleted] -- *Pottawattamie County/Province, KS, USA

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Foster County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, U.S.A

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cavalier County/Province, ND, USA

OR120018_BR_011222

CBI-DELETED

Monsanto Reference ID
2004-36XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(6)

ND

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.

[CBI Deleted] -- Foster County/Province, ND, U.S.A., 10 acres.

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.

[CBI Deleted] -- Cass County/Province, ND, USA, 10 acres.

[CBI Deleted] -- Cavalier County/Province, ND, USA, 10 acres.

OR120018_BR_011223

MONSANTO
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CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-36XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

January 20, 2004

OR120018_BR_011224

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

January 21, 2004

Dear Mr. Sim IV:

Enclosed is notification 04-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-021-05n Applicant #: 2004-36XRAB
Received: January 21, 2004 Effective: February 20, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO ND
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011225

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 21, 2004

Dear Dr. Hanks:

Enclosed is notification 04-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-021-05n Applicant #: 2004-36XRAB
Received: January 21, 2004 Effective: February 20, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO ND
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011226

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

January 21, 2004

Dear Mr. Brown:

Enclosed is notification 04-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-021-05n Applicant #: 2004-36XRAB
Received: January 21, 2004 Effective: February 20, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO ND
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011227

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 21, 2004

Dear Mr. Nelson:

Enclosed is notification 04-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-021-05n Applicant #: 2004-36XRAB
Received: January 21, 2004 Effective: February 20, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: KS MN MO ND
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011228

USDA United States Department of Agriculture | Animal and Plant Health Inspection Service | Biotechnology Regulatory Services | 4700 River Road, Unit 147 Riverdale, Maryland 20737-1236

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

January 21, 2004

Dear Dr. Hanks:

Enclosed is notification 04-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-021-05n	Applicant #:	2004-36XRAB
Received:	January 21, 2004	Effective:	February 20, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. movement only

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J Hanks

Signature: (b) (6), (b) (7)(C)

Date: 2-6-04

State: MN

Rptloc01/R4

OR120018_BR_011229

FEB 6 2004

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

January 21, 2004

Dear Mr. Nelson:

Enclosed is notification 04-021-05n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-021-05n	Applicant #:	2004-36XRAB
Received:	January 21, 2004	Effective:	February 20, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	KS MN MO ND		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. Attachment

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R Nelson

Signature: (b) (6), (b) (7)(C)

Date: 3-16-04

State: ND

Rptloc01/R4

OR120018_BR_011230

MAR 17 2004

March 17, 2004

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after March 17, 2004.**

Interstate movement and Release
Notification no. 04-021-05n (2004-36XRAB)
Regulated article - Wheat
Destinations - Kansas, Minnesota, Missouri, North Dakota

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of North Dakota has (attached) supplemental conditions.

In addition, the State of Minnesota concur for movement only.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
File number 04-021-05n

OR120018_BR_011231

AGRICULTURE COMMISSIONER
ROGER JOHNSON

PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: Mary Jackson
Biotechnology Program Operations – Permit Unit
USDA APHIS
4700 River Road
Riverdale MD 27037

FROM: David R. Nelson (b) (6), (b) (7)(C)
DATE: March 16, 2004
RE: Supplemental Conditions for Release of Wheat

Bp Number	Applicant Number	Institution
04-015-13n	2004-39XRAB	Monsanto
04-021-05n	2004-36XRAB	Monsanto
04-035-06n	2004-225XRAB	Monsanto
04-062-02n	2004-363XRAB	Monsanto
04-064-07n	2004-375XRAB	Monsanto
04-063-04n	SYN2004-107	Syngenta

The North Dakota Department of Agriculture concurs with the above mentioned notifications for transgenic wheat and suggests the following supplemental conditions. Thank you for the opportunity to comment.

North Dakota Supplemental Conditions 2004

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.

2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.

3. Because of the possibility of volunteers:

   - Wheat , or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.

   - If a transgenic wheat plot is harvested with a commercial combine (other than a small plot combine), then wheat or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown with the field trial area nor within 50 meters of the field trial area during the subsequent two growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.

- Consultation should occur with the North Dakota Agriculture Experiment Station Director and the NDSU Seedstocks Director prior to planting to assure that isolation of at least 330 feet from Foundation Seedstock production and other significant ND Agricultural Experiment Station plantings is maintained.

Confirmation Report–Memory Send

Time : Mar-19-04 09:53am
Tel line 1 :
Tel line 2 :
Name :

Job number : 667
Date : Mar-19 09:52am
To : 916367377085
Document Pages : 04
Start time : Mar-19 09:52am
End time : Mar-19 09:53am
Pages sent : 04
Job number : 667 *** SEND SUCCESSFUL ***

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

March 17, 2004

(b) (6), (b) (7)(C)
[redacted]
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after March 17, 2004.

Interstate movement and Release
Notification no. 04-021-05n (2004-36XRAB)
Regulated article - Wheat
Destinations - Kansas, Minnesota, Missouri, North Dakota

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of North Dakota has (attached) supplemental conditions.

In addition, the State of Minnesota concur for movement only.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)
[redacted]
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND

APHIS- Protecting American Agriculture
An Equal Opportunity Employer

OR120018_BR_011233

MONSANTO

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

April 7, 2004

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notifications:

USDA#	Monsanto#
02-022-57n	2002-256XRAB
02-051-19n	2002-457XRAB
03-015-10n	2003-22XRAB
03-052-27n	2003-205XRAB
04-021-05n	2004-36XRAB

The former name/address information is:

(b) (4)

(b) (4) Cavalier, ND, (b) (4) – **CBI**

The new name/address information is:

(b) (4)

Cavalier, ND (b) (4) – **CBI**

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

Cc: Ralph Stoaks

MONSANTO

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

CBI - DELETED

April 7, 2004

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notifications:

USDA#	Monsanto#
02-022-57n	2002-256XRAB
02-051-19n	2002-457XRAB
03-015-10n	2003-22XRAB
03-052-27n	2003-205XRAB
04-021-05n	2004-36XRAB

The former name/address information is:
[CBI DELETED] - Cavalier, ND

The new name/address information is:
[CBI DELETED] - Cavalier, ND

If you have any questions, please contact me at (b) (4)

Sincerely yours,

(b) (4)

Cc: Ralph Stoaks

CONFIDENTIAL

2004 Wheat Field Test Report
USDA #04-021-05n Monsanto #2004-36XRAB

February 16, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
2147307361	Cass	ND	
2147314745	Cass	ND	
1611677957	Foster	ND	Not Planted
2147307378	Cass	ND	
2147303287	Cass	ND	Not Planted
2147320702	Cavalier	ND	Not Planted

Cass County/ND (2147307361)

Planting Date: 05/04/2004

Destruct Date: 06/14/2004

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4) (b) (4) - CBI

Field Monitoring Observations for Disease Susceptibility: (b) (4) (b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4) (b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4) (b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4) (b) (4)

OR120018_BR_011236

2/17/05

Field Monitoring Observations for Plant Stand: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4) - CBI

Cass County/ND (2147314745)

Planting Date: 04/30/2004

Destruct Date: 06/14/2004

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4) - CBI

Field Monitoring Observations for Disease Susceptibility: (b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

Cass County/ND (2147307378)

Planting Date: 05/03/2004

Destruct Date: 07/09/2004

OR120018_BR_011237

Vector Constructs/Line Numbers Planted: (b) (4) CBI

Purpose of Field Trial: (b) (4)

Field Monitoring Observations for Disease Susceptibility: (b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

Additional Comments: (b) (4)

OR120018_BR_011238

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943#44 (lOth Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011239

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

OR120018_BR_011240

CBI-DELETED

2004 Wheat Field Test Report
USDA #04-021-05n Monsanto #2004-36XRAB

February 16, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
2147307361	Cass	ND	
2147314745	Cass	ND	
1611677957	Foster	ND	Not Planted
2147307378	Cass	ND	
2147303287	Cass	ND	Not Planted
2147320702	Cavalier	ND	Not Planted

Cass County/ND (2147307361)

Planting Date: 05/04/2004

Destruct Date: 06/14/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Cass County/ND (2147314745)

Planting Date: 04/30/2004

Destruct Date: 06/14/2004

OR120018_BR_011241

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Cass County/ND (2147307378)

Planting Date: 05/03/2004

Destruct Date: 07/09/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

OR120018_BR_011242

2/09/04 8:41 am Notification Tracking Sheet

==========
Bp number: 04-034-03n
==========

App number: 2004-155XRAB
Received: 2/03/04
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/04/04
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C)

Begin movement: 3/03/04
End movement: 3/03/05
Begin release: 3/03/04
End release: 3/03/05
Acre: 32.00
CBI status: CBI

Fax: 636-737-7085

		Initial	Date
1.	[✓] Assign Bp number and initial data entry	[apd]	[2/9/04]
2.	[✓] Review by biotechnologist	[mtw]*	[2/12/04]*
3.	[✓] Letter of notification to State Fed-ex	[KLO]	[2/19/04]*
4.	[ ] State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	CO	*	*WR	[ ]	[ ]
Interstate	*Dest*	MN	*	*NER	[ ]	[ ]
Interstate	*Dest*	MO	*	*SCR	[ ]	[ ]
Interstate	*Dest*	ND	*	*SCR	[ ]	[ ]
Interstate	*Dest*	SD	*	*SCR	[ ]	[ ]
Interstate	*Orig*	CO	*	*WR		
Interstate	*Orig*	MN	*	*NER		
Interstate	*Orig*	MO	*	*SCR		
Interstate	*Orig*	ND	*	*SCR		
Interstate	*Orig*	SD	*	*SCR		
Release	*	*MN	*	4*NER	[ ]	[ ]
Release	*	*SD	*	2*SCR	[ ]	[ ]

5.	[✓] Enter genes into database	[apd]	[2/12/04]
6.	[✓] Letter of acknowledgement/denial/withdraw	[KLO]	[3/26/04]*
7.	[✓] Enter final data into database	[KLO]	[4/8/04]
8.	[ ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

MONSANTO

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Monsanto Reference ID
2004-155XRAB

Permit Unit

February 2, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-034-03n

1. USDA Reference Number

2. Application Reference Number 2004-155XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Monsanto Company

Email (b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release March 3, 2004 - March 3, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

OR120018_BR_011244

Monsanto Reference ID
2004-155XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [redacted] (b) (4) [redacted] (b) (4) [redacted] *CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011245

Monsanto Reference ID
2004-155XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to _10,000_pounds wheat seed to and from each location.

ORIGIN:

CO, MN, MO, ND, SD

DESTINATION:

CO, MN, MO, ND, SD

Ship From/Ship To:

CO

*[(b) (4) Weld County/Province, CO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

MN

*[(b) (4) Polk County/Province, MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) Marshall County/Province, MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) Ramsey County/Province, MN, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)

OR120018_BR_011246

Monsanto Reference ID
2004-155XRAB

MN, 55108, U.S.A., 612/625-9763

]-CBI

*[(b) (4) Dakota County/Province, MN, (b) (4) U.S.A.

CONTACT (b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) Stevens County/Province, MN, (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

ND

*[(b) (4) Cass County/Province, ND (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

SD

*[(b) (4), (b) (6), (b) (7)(C) Brookings County/Province, SD, (b) (4), (b) (6), (b) (7)(C) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) SD, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

OR120018_BR_011247

Monsanto Reference ID
2004-155XRAB

]-CBI

* (b) (4), (b) (6), (b) (7)(C) Spink County/Province, SD [redacted] USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) SD, [redacted] USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4), (b) (6), (b) (7)(C) Codington County/Province, SD [redacted] USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) SD [redacted] USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) Brookings County/Province, SD (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) SD, [redacted] USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

OR120018_BR_011248

Monsanto Reference ID
2004-155XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(4), SD(2)

MN

[redacted] Polk County/Province, MN, [redacted] USA, 4 acres. (2147303429)

RESPONSIBLE PERSON/RESEARCHER: [redacted] MN [redacted] USA [redacted]

]-CBI

[redacted] Ramsey County/Province, MN, [redacted] U.S.A., 6 acres. (424036936)

RESPONSIBLE PERSON/RESEARCHER [redacted] MN, [redacted] U.S.A., [redacted]

]-CBI

[redacted] Dakota County/Province, MN [redacted] U.S.A., 6 acres. (8025)

RESPONSIBLE PERSON/RESEARCHER: [redacted] MN, [redacted] U.S.A., [redacted]

]-CBI

[redacted] Stevens County/Province, MN, [redacted] USA, 4 acres. (2147308819)

RESPONSIBLE PERSON/RESEARCHER: [redacted] MN, [redacted] USA, [redacted]

]-CBI

SD

[redacted] SD, [redacted] USA, 6 acres. (2147319744)

RESPONSIBLE PERSON/RESEARCHER: [redacted] SD [redacted] USA, [redacted]

OR120018_BR_011249

Monsanto Reference ID
2004-155XRAB

]-CBI

[redacted] Codington County/Province, SD, [redacted] USA, 6 acres. (2147317547)

RESPONSIBLE PERSON/RESEARCHER: [redacted] SD [redacted] USA, [redacted]

]-CBI

OR120018_BR_011250

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Monsanto Reference ID
2004-155XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 2, 2004

OR120018_BR_011251

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S. , 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982). Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Monsanto Reference ID
2004-155XRAB

Permit Unit

February 2, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-034-03n

1. USDA Reference Number

2. Application Reference Number 2004-155XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release March 3, 2004 - March 3, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

OR120018_BR_011255

CBI-DELETED

Monsanto Reference ID
2004-155XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] *CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011256

Monsanto Reference ID
2004-155XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to _10,000_pounds wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
CO, MN, MO, ND, SD	CO, MN, MO, ND, SD

Ship From/Ship To:

CO

[CBI Deleted] -- *Weld County/Province, CO, USA

MN

[CBI Deleted] -- *Polk County/Province, MN, USA

[CBI Deleted] -- *Marshall County/Province, MN, USA

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

[CBI Deleted] -- *Dakota County/Province, MN, U.S.A.

[CBI Deleted] -- *Stevens County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

[CBI Deleted] -- *Spink County/Province, SD, USA

[CBI Deleted] -- *Codington County/Province, SD, USA

OR120018_BR_011257

CBI-DELETED

Monsanto Reference ID
2004-155XRAB

[CBI Deleted] -- *Brookings County/Province, SD, USA

OR120018_BR_011258

CBI-DELETED

Monsanto Reference ID
2004-155XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(4), SD(2)

MN

[CBI Deleted] -- Polk County/Province, MN, USA, 4 acres.

[CBI Deleted] -- Ramsey County/Province, MN, U.S.A., 6 acres.

[CBI Deleted] -- Dakota County/Province, MN, U.S.A., 6 acres.

[CBI Deleted] -- Stevens County/Province, MN, USA, 4 acres.

SD

[CBI Deleted] -- Brookings County/Province, SD, USA, 6 acres.

[CBI Deleted] -- Codington County/Province, SD, USA, 6 acres.

OR120018_BR_011259

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Monsanto Reference ID
2004-155XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 2, 2004

OR120018_BR_011260

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Monsanto Reference ID
2004-155XRAB

Permit Unit

February 2, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-034-03n

1. USDA Reference Number

2. Application Reference Number 2004-155XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release March 3, 2004 - March 3, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

OR120018_BR_011261

CBI-DELETED

Monsanto Reference ID
2004-155XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011262

Monsanto Reference ID
2004-155XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to _10,000_pounds wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
CO, MN, MO, ND, SD	CO, MN, MO, ND, SD

Ship From/Ship To:

CO

[CBI Deleted] -- *Weld County/Province, CO, USA

MN

[CBI Deleted] -- *Polk County/Province, MN, USA

[CBI Deleted] -- *Marshall County/Province, MN, USA

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

[CBI Deleted] -- *Dakota County/Province, MN, U.S.A.

[CBI Deleted] -- *Stevens County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

[CBI Deleted] -- *Spink County/Province, SD, USA

[CBI Deleted] -- *Codington County/Province, SD, USA

OR120018_BR_011263

CBI-DELETED

Monsanto Reference ID
2004-155XRAB

[CBI Deleted] -- *Brookings County/Province, SD, USA

OR120018_BR_011264

CBI-DELETED

Monsanto Reference ID
2004-155XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(4), SD(2)

MN

[CBI Deleted] -- Polk County/Province, MN, USA, 4 acres.

[CBI Deleted] -- Ramsey County/Province, MN, U.S.A., 6 acres.

[CBI Deleted] -- Dakota County/Province, MN, U.S.A., 6 acres.

[CBI Deleted] -- Stevens County/Province, MN, USA, 4 acres.

SD

[CBI Deleted] -- Brookings County/Province, SD, USA, 6 acres.

[CBI Deleted] -- Codington County/Province, SD, USA, 6 acres.

OR120018_BR_011265

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Monsanto Reference ID
2004-155XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 2, 2004

OR120018_BR_011266

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

February 9, 2004

Dear Mr. Yergert:

Enclosed is notification 04-034-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-034-03n Applicant #: 2004-155XRAB
Received: February 3, 2004 Effective: March 4, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO MN MO ND SD
Release destination: MN SD

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(S)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011267

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 9, 2004

Dear Dr. Hanks:

Enclosed is notification 04-034-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-034-03n Applicant #: 2004-155XRAB
Received: February 3, 2004 Effective: March 4, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO MN MO ND SD
Release destination: MN SD

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011268

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 9, 2004

Dear Mr. Brown:

Enclosed is notification 04-034-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-034-03n Applicant #: 2004-155XRAB
Received: February 3, 2004 Effective: March 4, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO MN MO ND SD
Release destination: MN SD

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011269

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 9, 2004

Dear Mr. Nelson:

Enclosed is notification 04-034-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-034-03n Applicant #: 2004-155XRAB
Received: February 3, 2004 Effective: March 4, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO MN MO ND SD
Release destination: MN SD

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011270

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

February 9, 2004

Dear Mr. Fridley:

Enclosed is notification 04-034-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-034-03n Applicant #: 2004-155XRAB
Received: February 3, 2004 Effective: March 4, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO MN MO ND SD
Release destination: MN SD

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011271

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

February 9, 2004

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

Dear Mr. Yergert:

Enclosed is notification 04-034-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-034-03n Applicant #: 2004-155XRAB
Received: February 3, 2004 Effective: March 4, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO MN MO ND SD
Release destination: MN SD

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

__X__ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: MITCHELL YERGERT

Signature: Mitchell Yergert

Date: FEB. 20, 2004

State: COLORADO Rptloc01/R4

OR120018_BR_011272

FEB 20 2004

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 9, 2004

Dear Dr. Hanks:

Enclosed is notification 04-034-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-034-03n	Applicant #:	2004-155XRAB
Received:	February 3, 2004	Effective:	March 4, 2004
Institution:	Monsanto	Recipient:	Wheat

Interstate destination: CO MN MO ND SD
Release destination: MN SD

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. with additional conditions

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature (b) (6), (b) (7)(C)

Date: 3-18-04

State: MN

Rptloc01/R4

OR120018_BR_011273

MAR 19 2004

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 9, 2004

Dear Mr. Nelson:

Enclosed is notification 04-034-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-034-03n	Applicant #:	2004-155XRAB
Received:	February 3, 2004	Effective:	March 4, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MN MO ND SD		
Release destination:	MN SD		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: C. Dave R Nelson

Signature: (b) (6), (b) (7)(C)

Date: 4-16-04

State: ND

Rptloc01/R4

OR120018_BR_011274
MAR 16 2004
MAR.16.2004 7:40PM NO.801 P.4

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

February 9, 2004

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

Dear Mr. Fridley:

Enclosed is notification 04-034-03n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-034-03n
Received: February 3, 2004
Institution: Monsanto
Applicant #: 2004-155XRAB
Effective: March 4, 2004
Recipient: Wheat
Interstate destination: CO MN MO ND SD
Release destination: MN SD

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

FEB 2004 RECEIVED S. D. DEPT. OF AGRICULTURE

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination,

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 2/23/04

State: South Dakota

Rptloc01/R4

OR120018_BR_011275
FEB 24 2004

March 26, 2004

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after March 26, 2004.**

Interstate movement and Release
Notification no. 04-034-03n (2004-155XRAB)
Regulated article - Wheat
Destinations - Colorado, Minnesota, Missouri, North Dakota, South Dakota

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Minnesota concur with (attached) conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
M. Yergert, Colorado Dept. of Agric., Lakewood, CO
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 04-034-03n

OR120018_BR_011276

MINNESOTA DEPARTMENT OF AGRICULTURE
FROM THE FARM TO YOUR FAMILY

(651) 296-1277

March 18, 2004

Ms. Mary Jackson
Biotechnology Program Operations - Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

RE: Additional Conditions for Release of Wheat 04-034-03n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain must be at least 100 feet.
3. Because of the possibility of volunteers:
   - If trials are harvested by hand or with small plot equipment, wheat, or crops that would make locating or controlling volunteer wheat difficult (i.e. other small grains), should not be grown within the field trial area nor within a 33 feet isolation area around the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
   - If trials are harvested by commercial combine rather than by small plot combine, an additional 150 feet isolation area around the field trial area during the subsequent two (2) growing seasons is required.
4. Consultation should occur with the Minnesota Research and Outreach Center Directors at the release sites prior to planting to assure that isolation of at least 330 feet from foundation seedstock production and other significant plantings is maintained.

These conditions are in addition to those contained in the applicant's "Wheat Field Release Performance Standards" dated January 2004.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.
State Biotechnologist

OR120018_BR_01277

NOTIFICATION FIELD SITE INSPECTION WORKSHEET

When completed, this is an Internal PPQ Document

8/30/04

AHPIS Notification Number: 04-034-03n Crop: Wheat

Applicant's Name: (b) (6), (b) (7)(C) Trait/Gene: HT glyphosate tolerant

Name of Company & Cooperator at site: (b) (6), (b) (7)(C), (b) (4) Phone: (b) (6), (b) (7)(C), (b) (4)

Location of site: Brookings Co – (b) (6), (b) (7)(C), (b) (4) SD Date of Inspection: _____

Type of location: ☐ Farm ☐ Nursery ☐ Other (describe) _____

GPS/ GIS Coordinates (if available): Latitude _____ Longitude _____

Provide the answers below. Check "Y" for Yes and "N" for No. If the answer to any questions is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Regional Program Manager.

I. <u>Shipping, Maintenance at Destination, and Identification</u>

A. Did all aspects of field trail maintain identity (seed storage, planting & harvest site, borders, field cages, etc.)? Y☒ N☐

B. Was a site map obtained or drawn by your for reference later (For harvest, flower removal, volunteers, etc.)? Y☐ N☒

– Crop was planted & destroyed prior to inspection per Monsanto

II. <u>Field Test Site Requirements Addressing Inadvertent Mixing, Persistence, and Volunteer Plants</u>

A. If there were any other cultivated plantings of the crop within the vicinity of the field test, were they located outside the pollination distance for the crop? Y☒ N☐

B. If the transgenic plant is sexually compatible with free-living plants, were there no compatible species located within the pollination distance for the plants? Y☒ N☐

C. Which of the five containment options is the applicant using? Check one of the options below. If none, please note it here and state this in your cover letter to the Regional Program Manager. _____

1. Removing Flowers _____

   Is there any evidence that the plants have flowers or that flowers have been removed? Y☐ N☐

2. Bagging Flowers/Tassels _____

   Does the applicant have material to bag reproductive structures? Y☐ N☐

3. Terminating the experiment before flowering _____

   Were plants destroyed or removed from the field before any flowers were allowed to release pollen? Y☐ N☐

4. Physical Isolation _____

   If there are any non-transgenic compatible plants within the distance stated in Table 1 (for pollination distance), were they being treated as transgenic and disposed of and monitored for volunteers by the same methods used for the transgenic? Y☒ N☐

5. Temporal Isolation _____

   Is there evidence that the flowering times of the transgenic plant and any non-transgenic plants will not overlap and is the applicant monitoring the plants to ensure that flowering times do not overlap? Y☐ N☐

OR120018_BR_011278

D. If the applicant's design standards use border rows, are there the stated numbers of border rows? Y☐ N☐

E. Is there an alley or other marking system to separate any transgenic plant from non-transgenic? Y☐ N☐

Plants of the same species? Y☐ N☐

F. If transgenic plants were grown the previous year, were volunteers removed according to the design standards? Y☐ N☐

G. Does the applicant anticipate volunteers and have the necessary chemical or equipment as stated in their design standards? Y☐ N☐

H. Was the field site marked as stated in the design standards? Y☐ N☐

I. Does the applicant have an area designated to clean the machinery that may contain seeds or reproductive parts? Y☐ N☐

J. If seeds or reproductive parts are washed off the equipment, does the applicant have a way to ensure that they do not survive? Y☐ N☐

III. Devitalization

A. Does the applicant have the necessary equipment to devitalize the plant material as described? Y☒ N☐

In the design standards (e.g., an autoclave, steamer, burial pit, incineration)? Y☒ N☐

B. Remind applicant that their transgenic plants cannot be used for food or feed unless consultation with the Food and Drug Administration (FDA) regarding the transgenic plants has been successfully completed and approved.

The signed original of this report was furnished to Juan Roman, APHIS, BRS Y☒ N☐

Inspecting Officer Signature: (b) (6), (b) (7)(C)

Printed Name: Amy Meshan

Phone: 605-224-1713 Location of PPQ Officer: Pierre SD

Names and Affiliation of Any Other Persons at the inspection:

Please fax/ email completed worksheet to:	*Please FedEx original worksheet to:*
Ralph Stoaks, Regional Biotechnologist	*Juan Roman, Chief Biotechnology Program Operations*
2150 Centre Ave. Bldg. B, 3E10	*4700 River Road, Unit 147, 5B53*
Ft. Collins, CO 80526	*Riverdale, MD 20737*
Phone: 970-494-7573 Fax: 970-494-7576	*Phone: 301-734-0029*
Email: ralph.d.stoaks@aphis.usda.gov	

Revised
3/11/04

OR120018_BR_011279

MONSANTO

MONSANTO COMPANY
800 NORTH LINDBERGH BOULEVARD
ST. LOUIS, MISSOURI 63167
PHONE (314) 694-1000
http://www.monsanto.com

NO CBI

March 11, 2005

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

Monsanto is submitting the Field Test Report(s) for the following notification(s):

USDA	Monsanto#
04-034-03n	2004-155XRAB

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

epd
3/14/05

CONFIDENTIAL

2004 Wheat Field Test Report
USDA #04-034-03n Monsanto #2004-155XRAB

March 11, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
2147303429	Polk	MN	
424036936	Ramsey	MN	
8025	Dakota	MN	Not Planted
2147308819	Stevens	MN	
2147319744	Brookings	SD	
2147317547	Codington	SD	

Polk County/MN (2147303429)

Planting Date: 05/03/2004

Destruct Date: 06/10/2004

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4) - CBI

Field Monitoring Observations for Disease Susceptibility: (b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

OR120018_BR_011281

3/14/04

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

(b) (4)

Ramsey County/MN (424036936)

Planting Date: 05/04/2004

Harvest Date: 08/20/2004

Destruct Date: 09/14/2004

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4)

(b) (4)

Field Monitoring Observations for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

(b) (4)

Disposition of the Harvested Material: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

(b) (4)

Additional Comments:
CBI (b) (4)

Stevens County/MN (2147308819)

Planting Date: 05/03/2004

Destruct Date: 06/17/2004

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4) - CBI

Field Monitoring Observations for Disease Susceptibility: (b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

Brookings County/SD (2147319744)

Planting Date: 05/05/2004

Harvest Date: 08/22/2004

Destruct Date: 08/31/2004

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4)

OR120018_BR_011283

Field Monitoring Observations for Disease Susceptibility: (b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

Disposition of the Harvested Material: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

Additional Comments: (b) (4)

Codington County/SD (2147317547)

Planting Date: 04/28/2004

Destruct Date: 07/20/2004

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring Observations for Disease Susceptibility: (b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

OR120018_BR_011284

(b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

(b) (4)

Additional Comments: (b) (4)

OR120018_BR_011285

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943#44 (lOth Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011286

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

OR120018_BR_011287

MONSANTO

MONSANTO COMPANY
800 NORTH LINDBERGH BOULEVARD
ST. LOUIS, MISSOURI 63167
PHONE (314) 694-1000
http://www.monsanto.com

NO CBI

March 11, 2005

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

Monsanto is submitting the Field Test Report(s) for the following notification(s):

USDA	Monsanto#
04-034-03n	2004-155XRAB

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

opd 3/14/05

CBI-DELETED

2004 Wheat Field Test Report
USDA #04-034-03n Monsanto #2004-155XRAB

March 11, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
2147303429	Polk	MN	
424036936	Ramsey	MN	
8025	Dakota	MN	Not Planted
2147308819	Stevens	MN	
2147319744	Brookings	SD	
2147317547	Codington	SD	

Polk County/MN (2147303429)

Planting Date: 05/03/2004

Destruct Date: 06/10/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Ramsey County/MN (424036936)

Planting Date: 05/04/2004

Harvest Date: 08/20/2004

OR120018_BR_011289

3/14/05

Destruct Date: 09/14/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Stevens County/MN (2147308819)

Planting Date: 05/03/2004

Destruct Date: 06/17/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Brookings County/SD (2147319744)

Planting Date: 05/05/2004

OR120018_BR_011290

Harvest Date: 08/22/2004

Destruct Date: 08/31/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Codington County/SD (2147317547)

Planting Date: 04/28/2004

Destruct Date: 07/20/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

OR120018_BR_011291

2/19/04 3:46 pm Notification Tracking Sheet

==========
Bp number: 04-035-06n
==========

App number: 2004-225XRAB
Received: 2/04/04
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/05/04
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

Begin movement: 3/04/04
End movement: 3/04/05
Begin release: 3/04/04
End release: 3/04/05
Acre: 10.00
CBI status: CBI

		Initial	Date
1.	[✓] Assign Bp number and initial data entry	[ajd]	[2/23/04]
2.	[✓] Review by biotechnologist	[MTW]*	[2/24/04]*
3.	[✓] Letter of notification to State Fed-ex	[KLO]	[2/27/04]*
4.	[ ] State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	CO	*	*WR *	[ ]	[ ]
Interstate	*Dest*	KS	*	*SCR *	[ ]	[ ]
Interstate	*Dest*	MN	*	*NER *	[ ]	[ ]
Interstate	*Dest*	MO	*	*SCR *	[ ]	[ ]
Interstate	*Dest*	ND	*	*SCR *	[ ]	[ ]
Interstate	*Orig*	CO	*	*WR *		
Interstate	*Orig*	KS	*	*SCR *		
Interstate	*Orig*	MN	*	*NER *		
Interstate	*Orig*	MO	*	*SCR *		
Interstate	*Orig*	ND	*	*SCR *		
Release	*	*MN	*	1*NER *	[ ]	[ ]
Release	*	*ND	*	1*SCR *	[ ]	[ ]

5.	[✓] Enter genes into database	[ajd]	[2/24/04]
6.	[✓] Letter of acknowledgement/denial/withdraw	[KLO]	[3/26/04]*
7.	[✓] Enter final data into database	[KLO]	[4/8/04]
8.	[ ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

MONSANTO

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Monsanto Reference ID
2004-225XRAB

Permit Unit

February 3, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

1. USDA Reference Number 04-035-06n

2. Application Reference Number 2004-225XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release March 4, 2004 - March 4, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

OR120018_BR_011293

Monsanto Reference ID
2004-225XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [redacted] (b) (4) [redacted] (b) (4) *CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011294

Monsanto Reference ID
2004-225XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 lbs. Ship up to _10,000__pounds wheat seed to and from each location.

ORIGIN:

CO, KS, MN, MO, ND

DESTINATION:

CO, KS, MN, MO, ND

Ship From/Ship To:

CO

* (b) (4) Weld County/Province, CO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

]-CBI

KS

* (b) (4) Geary County/Province, KS, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) KS, (b) (4), (b) (6), (b) (7)(C) USA,

]-CBI

MN

* (b) (4) Polk County/Province, MN, (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

]-CBI

MO

* (b) (4) St. Louis County/Province, MO,

OR120018_BR_011295

Monsanto Reference ID
2004-225XRAB

(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

ND

*[(b) (4) Walsh County/Province, ND, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

OR120018_BR_011296

Monsanto Reference ID
2004-225XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1), ND(1)

MN

[(b) (4) Polk County/Province, MN,(b) (4) USA, 6 acres. (2147315828)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) CO (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

ND

[(b) (4) Walsh County/Province, ND,(b) (4) U.S.A., 4 acres. (-1119659810)

RESPONSIBLE PERSON/RESEARCHER (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) CO (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

OR120018_BR_011297

MONSANTO

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Monsanto Reference ID
2004-225XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 3, 2004

OR120018_BR_011298

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S. , 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982). Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Monsanto Reference ID
2004-225XRAB

Permit Unit

February 3, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

1. USDA Reference Number 04-035-06n

2. Application Reference Number 2004-225XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C) monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release March 4, 2004 - March 4, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

OR120018_BR_011302

CBI-DELETED

Monsanto Reference ID
2004-225XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011303

CBI-DELETED

Monsanto Reference ID
2004-225XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 lbs. Ship up to _10,000__pounds wheat seed to and from each location.

ORIGIN:

CO, KS, MN, MO, ND

DESTINATION:

CO, KS, MN, MO, ND

Ship From/Ship To:

CO

[CBI Deleted] -- *Weld County/Province, CO, USA

KS

[CBI Deleted] -- *Geary County/Province, KS, USA

MN

[CBI Deleted] -- *Polk County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Walsh County/Province, ND, U.S.A.

OR120018_BR_011304

CBI-DELETED

Monsanto Reference ID
2004-225XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1), ND(1)

MN

[CBI Deleted] -- Polk County/Province, MN, USA, 6 acres.

ND

[CBI Deleted] -- Walsh County/Province, ND, U.S.A., 4 acres.

OR120018_BR_011305

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Monsanto Reference ID
2004-225XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 3, 2004

OR120018_BR_011306

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Monsanto Reference ID
2004-225XRAB

Permit Unit

February 3, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

1. USDA Reference Number 04-035-06n

2. Application Reference Number 2004-225XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Monsanto Company

Email (b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release March 4, 2004 - March 4, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

OR120018_BR_011307

CBI-DELETED

Monsanto Reference ID
2004-225XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011308

CBI-DELETED

Monsanto Reference ID
2004-225XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 lbs. Ship up to _10,000__pounds wheat seed to and from each location.

ORIGIN:

CO, KS, MN, MO, ND

DESTINATION:

CO, KS, MN, MO, ND

Ship From/Ship To:

CO

[CBI Deleted] -- *Weld County/Province, CO, USA

KS

[CBI Deleted] -- *Geary County/Province, KS, USA

MN

[CBI Deleted] -- *Polk County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Walsh County/Province, ND, U.S.A.

OR120018_BR_011309

CBI-DELETED

Monsanto Reference ID
2004-225XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1), ND(1)

MN

[CBI Deleted] -- Polk County/Province, MN, USA, 6 acres.

ND

[CBI Deleted] -- Walsh County/Province, ND, U.S.A., 4 acres.

OR120018_BR_011310

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY NORTH
CHESTERFIELD, MISSOURI 63198
http://www.monsanto.com

Monsanto Reference ID
2004-225XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 3, 2004

OR120018_BR_011311

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

February 19, 2004

Dear Mr. Yergert:

Enclosed is notification 04-035-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-035-06n Applicant #: 2004-225XRAB
Received: February 4, 2004 Effective: March 5, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO KS MN MO ND
Release destination: MN ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011312

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Tom Sim IV, Administrator
Plant Protection and Weed Control Section
Kansas State Board of Agriculture
901 S. Kansas Avenue
Topeka, KS 66612-1281

February 19, 2004

Dear Mr. Sim IV:

Enclosed is notification 04-035-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-035-06n Applicant #: 2004-225XRAB
Received: February 4, 2004 Effective: March 5, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO KS MN MO ND
Release destination: MN ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011313

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 19, 2004

Dear Dr. Hanks:

Enclosed is notification 04-035-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-035-06n Applicant #: 2004-225XRAB
Received: February 4, 2004 Effective: March 5, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO KS MN MO ND
Release destination: MN ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011314

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

February 19, 2004

Dear Mr. Brown:

Enclosed is notification 04-035-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-035-06n Applicant #: 2004-225XRAB
Received: February 4, 2004 Effective: March 5, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO KS MN MO ND
Release destination: MN ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011315

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 19, 2004

Dear Mr. Nelson:

Enclosed is notification 04-035-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-035-06n	Applicant #:	2004-225XRAB
Received:	February 4, 2004	Effective:	March 5, 2004
Institution:	Monsanto	Recipient:	Wheat

Interstate destination: CO KS MN MO ND
Release destination: MN ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011316

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

February 19, 2004

Dear Mr. Yergert:

Enclosed is notification 04-035-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-035-06n	Applicant #:	2004-225XRAB
Received:	February 4, 2004	Effective:	March 5, 2004
Institution:	Monsanto	Recipient:	Wheat

Interstate destination: CO KS MN MO ND
Release destination: MN ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

__X__ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: (b) (6), (b) (7)(C)

Date: MARCH 1, 2004

State: COLORADO

Rptloc01/R4

MAR 1 2004

OR120018_BR_011317

USDA United States Department of Agriculture | Animal and Plant Health Inspection Service | Biotechnology Regulatory Services | 4700 River Road, Unit 147 Riverdale, Maryland 20737-1236

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

February 19, 2004

Dear Dr. Hanks:

Enclosed is notification 04-035-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-035-06n Applicant #: 2004-225XRAB
Received: February 4, 2004 Effective: March 5, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO KS MN MO ND
Release destination: MN ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. with conditions

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 3-19-04

State: MN

Rptloc01/R4

OR120018_BR_011318

MAR 19 2004

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

February 19, 2004

Dear Mr. Nelson:

Enclosed is notification 04-035-06n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-035-06n Applicant #: 2004-225XRAB
Received: February 4, 2004 Effective: March 5, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO KS MN MO ND
Release destination: MN ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State Official: David R Nelson

Signature: (b) (6), (b) (7)(C)

Date: 3-16-04

State: ND

Rptloc01/R4

OR120018_BR_011319
MAR 17 2004

March 26, 2004

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after March 26, 2004.**

Interstate movement and Release
Notification no. 04-035-06n (2004-225XRAB)
Regulated article - Wheat
Destinations - Colorado, Kansas, Minnesota, Missouri, North Dakota

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of Minnesota concur with (attached) conditions.

In addition, the State of North Dakota concur with the (attached) supplemental conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
M. Yergert, Colorado Dept. of Agric., Lakewood, CO
T. Sim, Kansas State Board of Agric., Topeka, KS
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
File number 04-035-06n

OR120018_BR_011320

MINNESOTA DEPARTMENT OF AGRICULTURE
FROM THE FARM TO YOUR FAMILY

(651) 296-1277

March 19, 2004

Ms. Mary Jackson
Biotechnology Program Operations - Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

RE: Additional Conditions for Release of Wheat 04-035-06n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain must be at least 100 feet.
3. Because of the possibility of volunteers:
   - If trials are harvested by hand or with small plot equipment, wheat, or crops that would make locating or controlling volunteer wheat difficult (i.e. other small grains), should not be grown within the field trial area nor within a 33 feet isolation area around the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
   - If trials are harvested by commercial combine rather than by small plot combine, an additional 150 feet isolation area around the field trial area during the subsequent two (2) growing seasons is required.
4. Consultation should occur with the Minnesota Research and Outreach Center Directors at the release sites prior to planting to assure that isolation of at least 330 feet from foundation seedstock production and other significant plantings is maintained.

These conditions are in addition to those contained in the applicant's "Wheat Field Release Performance Standards" dated January 2004.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.
State Biotechnologist

OR120018_BR_011321

AGRICULTURE COMMISSIONER
ROGER JOHNSON

PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: Mary Jackson
Biotechnology Program Operations – Permit Unit
USDA APHIS
4700 River Road
Riverdale MD 27037

FROM: David R. Nelson (b) (6), (b) (7)(C)
DATE: March 16, 2004
RE: Supplemental Conditions for Release of Wheat

Bp Number	Applicant Number	Institution
04-015-13n	2004-39XRAB	Monsanto
04-021-05n	2004-36XRAB	Monsanto
* 04-035-06n	2004-225XRAB	Monsanto
04-062-02n	2004-363XRAB	Monsanto
04-064-07n	2004-375XRAB	Monsanto
04-063-04n	SYN2004-107	Syngenta

The North Dakota Department of Agriculture concurs with the above mentioned notifications for transgenic wheat and suggests the following supplemental conditions. Thank you for the opportunity to comment.

North Dakota Supplemental Conditions 2004

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.

2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.

3. Because of the possibility of volunteers:

   - Wheat , or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.

   - If a transgenic wheat plot is harvested with a commercial combine (other than a small plot combine), then wheat or crops that would make locating or controlling volunteer wheat difficult (e.g, other small grains), should not be grown with the field trial area nor within 50 meters of the field trial area during the subsequent two growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.

- Consultation should occur with the North Dakota Agriculture Experiment Station Director and the NDSU Seedstocks Director prior to planting to assure that isolation of at least 330 feet from Foundation Seedstock production and other significant ND Agricultural Experiment Station plantings is maintained.

No CBI

2004 Wheat Field Test Report
USDA #04-035-06n Monsanto #2004-225XRAB

March 9, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
2147315828	Polk	MN	Not Planted
-1119659810	Walsh	ND	Not Planted

OR120018_BR_011323

3/11/05

3/02/04 10:31 am Notification Tracking Sheet

==========
Bp number: 04-056-09n
==========

App number: 2004-336XRAB
Received: 2/25/04
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 3/26/04
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C)

Begin movement: 3/25/04
End movement: 3/25/05
Begin release: 3/25/04
End release: 3/25/05
Acre: 25.00
CBI status: CBI

(b) (6), (b) (7)(C)

Fax: 636-737-7085

		Initial	Date
1.	[✓] Assign Bp number and initial data entry	[apl]	[3/2/04]
2.	[✓] Review by biotechnologist	[mtw]*	[3/2/04]*
3.	[✓] Letter of notification to State Fed-ex	[KLD]	[3/5/04]*
4.	[ ] State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	MN	*	*NER *	[ ]	[ ]
Interstate	*Dest*	MO	*	*SCR *	[ ]	[ ]
Interstate	*Dest*	ND	*	*SCR *	[ ]	[ ]
Interstate	*Orig*	MN	*	*NER *		
Interstate	*Orig*	MO	*	*SCR *		
Interstate	*Orig*	ND	*	*SCR *		
Release	*	*MN	*	1*NER *	[ ]	[ ]

5.	[✓] Enter genes into database	[apl]	[3/2/04]
6.	[✓] Letter of acknowledgement/denial/withdraw	[KLD]	[3/26/04]*
7.	[✓] Enter final data into database	[KLD]	[4/1/04]
8.	[ ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

5/3

MONSANTO

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-336XRAB

Permit Unit

February 24, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-056-09n

1. USDA Reference Number

2. Application Reference Number 2004-336XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Monsanto Company

Email (b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release March 25, 2004 - March 25, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): BW 251, BW 252, Alsen

OR120018_BR_011325

Monsanto Reference ID
2004-336XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [redacted] (b) (4) [redacted] (b) (4) *CBI*

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011326

Monsanto Reference ID
2004-336XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

Ship up to 100,000 pounds of wheat seed to/from each site.

ORIGIN:

MN, MO, ND

DESTINATION:

MN, MO, ND

Ship From/Ship To:

MN

*[(b) (4), (b) (6), (b) (7)(C) Marshall County/Province, MN, [redacted] USA

CONTACT [redacted] (b) (4), (b) (6), (b) (7)(C) MN, [redacted] USA,

]-CBI

MO

*[(b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT [redacted] (b) (4), (b) (6), (b) (7)(C) MO, [redacted] USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

ND

* (b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT [redacted] (b) (4), (b) (6), (b) (7)(C) ND, [redacted] USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

OR120018_BR_011327

Monsanto Reference ID
2004-336XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1)

MN

[redacted] Marshall County/Province, MN, [redacted] USA, 25 acres. (2147320202)

RESPONSIBLE PERSON/RESEARCHER: [redacted] MN, [redacted] USA, [redacted]

]-CBI

OR120018_BR_011328

MONSANTO

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-336XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 24, 2004

OR120018_BR_011329

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S. , 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982). Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-336XRAB

Permit Unit

February 24, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

1. USDA Reference Number 04-056-09n

2. Application Reference Number 2004-336XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C) monsanto.com

4. Duration of Introduction

Interstate Movement and Release March 25, 2004 - March 25, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): BW 251, BW 252, Alsen

OR120018_BR_011333

CBI-DELETED

Monsanto Reference ID
2004-336XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011334

CBI-DELETED

Monsanto Reference ID
2004-336XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

Ship up to 100,000 pounds of wheat seed to/from each site.

ORIGIN:

MN, MO, ND

DESTINATION:

MN, MO, ND

Ship From/Ship To:

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

OR120018_BR_011335

Monsanto Reference ID
2004-336XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1)

MN

[CBI Deleted] -- Marshall County/Province, MN, USA, 25 acres.

OR120018_BR_011336

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-336XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 24, 2004

OR120018_BR_011337

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-336XRAB

Permit Unit

February 24, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-056-09n

1. USDA Reference Number

2. Application Reference Number 2004-336XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Monsanto Company

Email (b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release March 25, 2004 - March 25, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): BW 251, BW 252, Alsen

OR120018_BR_011338

CBI-DELETED

Monsanto Reference ID
2004-336XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011339

CBI-DELETED

Monsanto Reference ID
2004-336XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

Ship up to 100,000 pounds of wheat seed to/from each site.

ORIGIN:

MN, MO, ND

DESTINATION:

MN, MO, ND

Ship From/Ship To:

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

OR120018_BR_011340

CBI-DELETED

Monsanto Reference ID
2004-336XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MN(1)

MN

[CBI Deleted] -- Marshall County/Province, MN, USA, 25 acres.

OR120018_BR_011341

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-336XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

February 24, 2004

OR120018_BR_011342

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

March 2, 2004

Dear Dr. Hanks:

Enclosed is notification 04-056-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-056-09n	Applicant #:	2004-336XRAB
Received:	February 25, 2004	Effective:	March 26, 2004
Institution:	Monsanto	Recipient:	Wheat

Interstate destination: MN MO ND
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011343

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

March 2, 2004

Dear Mr. Brown:

Enclosed is notification 04-056-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-056-09n Applicant #: 2004-336XRAB
Received: February 25, 2004 Effective: March 26, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: MN MO ND
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011344

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 2, 2004

Dear Mr. Nelson:

Enclosed is notification 04-056-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-056-09n	Applicant #:	2004-336XRAB
Received:	February 25, 2004	Effective:	March 26, 2004
Institution:	Monsanto	Recipient:	Wheat

Interstate destination: MN MO ND
Release destination: MN

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

MJ

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011345

04-056-09n

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

March 2, 2004

Dear Dr. Hanks:

Enclosed is notification 04-056-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-056-09n
Received: February 25, 2004
Institution: Monsanto
Interstate destination: MN MO ND
Release destination: MN
Applicant #: 2004-336XRAB
Effective: March 26, 2004
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. with conditions

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 3-19-04

State: MN

Rptloc01/R4

OR120018_BR_011346

MAR 19 2004

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 2, 2004

Dear Mr. Nelson:

Enclosed is notification 04-056-09n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-056-09n	Applicant #:	2004-336XRAB
Received:	February 25, 2004	Effective:	March 26, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MN MO ND		
Release destination:	MN		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

__X__ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R Nelson

Signature: (b) (6), (b) (7)(C)

Date: 4-16-04

State: ND

Rptloc01/R4

OR120018_BR_011347
MAR 16 2004
MAR.16.2004 7:40PM NO.801 P.3

March 26, 2004

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after March 26, 2004.**

Interstate movement and Release
Notification no. 04-056-09n (2004-336XRAB)
Regulated article - Wheat
Destinations - Minnesota, Missouri, North Dakota

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

In addition, the State of Minnesota concur with the (attached) conditions.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
File number 04-056-09n

MINNESOTA DEPARTMENT OF AGRICULTURE
FROM THE FARM TO YOUR FAMILY

(651) 296-1277

March 19, 2004

Ms. Mary Jackson
Biotechnology Program Operations - Permit Unit
USDA APHIS
4700 River Road
Riverdale, MD 27037

RE: Additional Conditions for Release of Wheat 04-056-09n

The State of Minnesota concurs with the above mentioned notification for the release of herbicide tolerant wheat with the following additional conditions:

If the regulated material (wheat) is to be allowed to flower, the

1. Isolation from wheat that will be harvested for use as seed must be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.
2. Isolation from any wheat that will be harvested for grain must be at least 100 feet.
3. Because of the possibility of volunteers:
   - If trials are harvested by hand or with small plot equipment, wheat, or crops that would make locating or controlling volunteer wheat difficult (i.e. other small grains), should not be grown within the field trial area nor within a 33 feet isolation area around the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.
   - If trials are harvested by commercial combine rather than by small plot combine, an additional 150 feet isolation area around the field trial area during the subsequent two (2) growing seasons is required.
4. Consultation should occur with the Minnesota Research and Outreach Center Directors at the release sites prior to planting to assure that isolation of at least 330 feet from foundation seedstock production and other significant plantings is maintained.

These conditions are in addition to those contained in the applicant's "Wheat Field Release Performance Standards" dated January 2004.

The State believes that the requirement that "no offspring can be produced that could persist in the environment" cannot be met under current APHIS guidelines that utilize methods that are used to ensure purity of certified seed. The needs of seed certification differ from the need to prevent persistence in the environment. The additional conditions that Minnesota is requiring for the release of this genetically engineered wheat in this state will prevent the regulated material from the field trial from persisting in the environment by minimizing the likelihood of pollination and successful fertilization of receptive plants outside of the field trial both during the year of the field trial and subsequent years.

Sincerely,

(b) (6), (b) (7)(C)

Mary J. Hanks, Ph.D.
State Biotechnologist

ORI20018_BR_011349

No CBI

2004 Wheat Field Test Report
USDA #04-056-09n Monsanto #2004-336XRAB

March 9, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
2147320202	Marshall	MN	Not Planted

OR120018_BR_011350

DMM 3/11/05

3/05/04 3:13 pm Notification Tracking Sheet

==========
Bp number: 04-062-02n
==========

App number: 2004-363XRAB
Received: 3/02/04
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 4/01/04
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

Begin movement: 3/31/04
End movement: 3/31/05
Begin release: 3/31/04
End release: 3/31/05
Acre: 16.00
CBI status: CBI

		Initial	Date
1.	[✓] Assign Bp number and initial data entry	[ajd]	[3/9/04]
2.	[✓] Review by biotechnologist	[JMA]*	[3/9/04]*
3.	[✓] Letter of notification to State Fed-ex	[KLO]	[3/11/04]*
4.	[ ] State response		

O/d	Loc	Site	Reg		
Interstate	*Dest*	CO	*WR*	[ ]	[ ]
Interstate	*Dest*	MN	*NER*	[ ]	[ ]
Interstate	*Dest*	MO	*SCR*	[ ]	[ ]
Interstate	*Dest*	ND	*SCR*	[ ]	[ ]
Interstate	*Dest*	SD	*SCR*	[ ]	[ ]
Interstate	*Orig*	CO	*WR*		
Interstate	*Orig*	MN	*NER*		
Interstate	*Orig*	MO	*SCR*		
Interstate	*Orig*	ND	*SCR*		
Interstate	*Orig*	SD	*SCR*		
Release	*	ND	3*SCR*	[ ]	[ ]

5.	[✓] Enter genes into database	[ajd]	[3/9/04]
6.	[✓] Letter of acknowledgement/denial/withdraw	[KLO]	[4/20/04]*
7.	[✓] Enter final data into database	[KLO]	[4/13/04]
8.	[ ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

MONSANTO

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-363XRAB

Permit Unit

March 1, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-062-02n

1. USDA Reference Number

2. Application Reference Number 2004-363XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release March 31, 2004 - March 31, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

OR120018_BR_011352

Monsanto Reference ID
2004-363XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4) (b) (4) ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011353

Monsanto Reference ID
2004-363XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

15,000 lbs Ship up to _15,000_____pounds wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
CO, MN, MO, ND, SD	CO, MN, MO, ND, SD

Ship From/Ship To:

CO

*[(b) (4) Weld County/Province, CO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CO, (b) (4), (b) (6), (b) (7)(C) USA,

]-CBI

MN

* (b) (4) Marshall County/Province, MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MN, (b) (4), (b) (6), (b) (7)(C) USA,

]-CBI

*[(b) (4) Ramsey County/Province, MN (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
MN (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

]-CBI

MO

* (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C) MO,

OR120018_BR_011354

Monsanto Reference ID
2004-363XRAB

63017, USA, 636/737-7661

]-CBI

ND

*[(b) (4) Cass County/Province, ND (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) Adams County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) Ward County/Province, ND, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(ND, (b) (4), (b) (6), (b) (U.S.A. (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7)(USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

SD

OR120018_BR_011355

Monsanto Reference ID
2004-363XRAB

[redacted] Brookings County/Province, SD, [redacted] USA

CONTACT: [redacted]

[redacted] SD [redacted] USA [redacted]

]-CBI

OR120018_BR_011356

Monsanto Reference ID
2004-363XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(3)

ND

[redacted] Cass County/Province, ND, [redacted] USA, 8 acres. (2147320162)

RESPONSIBLE PERSON/RESEARCHER: [redacted] ND, [redacted] USA

]-CBI

[redacted] Adams County/Province, ND, [redacted] USA, 4 acres. (2147320143)

RESPONSIBLE PERSON/RESEARCHER: [redacted] ND, [redacted] USA

]-CBI

[redacted] Ward County/Province, ND, [redacted] U.S.A., 4 acres. (2147310478)

RESPONSIBLE PERSON/RESEARCHER: [redacted] ND, [redacted] U.S.A.

]-CBI

OR120018_BR_011357

MONSANTO

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-363XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 1, 2004

OR120018_BR_011358

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S. , 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982). Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-363XRAB

Permit Unit

March 1, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-062-02n

1. USDA Reference Number

2. Application Reference Number 2004-363XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release March 31, 2004 - March 31, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

OR120018_BR_011362

CBI-DELETED

Monsanto Reference ID
2004-363XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011363

CBI-DELETED

Monsanto Reference ID
2004-363XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

15,000 lbs Ship up to _15,000_____pounds wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
CO, MN, MO, ND, SD	CO, MN, MO, ND, SD

Ship From/Ship To:

CO

[CBI Deleted] -- *Weld County/Province, CO, USA

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Adams County/Province, ND, USA

[CBI Deleted] -- *Ward County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

OR120018_BR_011364

CBI-DELETED

Monsanto Reference ID
2004-363XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(3)

ND

[CBI Deleted] -- Cass County/Province, ND, USA, 8 acres.

[CBI Deleted] -- Adams County/Province, ND, USA, 4 acres.

[CBI Deleted] -- Ward County/Province, ND, U.S.A., 4 acres.

OR120018_BR_011365

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-363XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 1, 2004

OR120018_BR_011366

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-363XRAB

Permit Unit

March 1, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-062-02n

1. USDA Reference Number

2. Application Reference Number 2004-363XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Monsanto Company

Email (b) (6), (b) (7)(C)@monsanto.com

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release March 31, 2004 - March 31, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

OR120018_BR_011367

CBI-DELETED

Monsanto Reference ID
2004-363XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011368

CBI-DELETED

Monsanto Reference ID
2004-363XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

15,000 lbs Ship up to _15,000_____pounds wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
CO, MN, MO, ND, SD	CO, MN, MO, ND, SD

Ship From/Ship To:

CO

[CBI Deleted] -- *Weld County/Province, CO, USA

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

ND

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Adams County/Province, ND, USA

[CBI Deleted] -- *Ward County/Province, ND, U.S.A.

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

OR120018_BR_011369

CBI-DELETED

Monsanto Reference ID
2004-363XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

ND(3)

ND

[CBI Deleted] -- Cass County/Province, ND, USA, 8 acres.

[CBI Deleted] -- Adams County/Province, ND, USA, 4 acres.

[CBI Deleted] -- Ward County/Province, ND, U.S.A., 4 acres.

OR120018_BR_011370

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-363XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 1, 2004

OR120018_BR_011371

file copy

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

March 5, 2004

Dear Mr. Yergert:

Enclosed is notification 04-062-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-062-02n Applicant #: 2004-363XRAB
Received: March 2, 2004 Effective: April 1, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO MN MO ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011372

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

March 5, 2004

Dear Dr. Hanks:

Enclosed is notification 04-062-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-062-02n Applicant #: 2004-363XRAB
Received: March 2, 2004 Effective: April 1, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO MN MO ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011373

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

March 5, 2004

Dear Mr. Brown:

Enclosed is notification 04-062-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-062-02n Applicant #: 2004-363XRAB
Received: March 2, 2004 Effective: April 1, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO MN MO ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011374

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 5, 2004

Dear Mr. Nelson:

Enclosed is notification 04-062-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-062-02n Applicant #: 2004-363XRAB
Received: March 2, 2004 Effective: April 1, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO MN MO ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011375

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

March 5, 2004

Dear Mr. Fridley:

Enclosed is notification 04-062-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-062-02n Applicant #: 2004-363XRAB
Received: March 2, 2004 Effective: April 1, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO MN MO ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011376

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

March 5, 2004

Mr. Mitch Yergert
Colorado Department of Agriculture
700 Kipling Street - Suite 4000
Lakewood, CO 80215-5894

Dear Mr. Yergert:

Enclosed is notification 04-062-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-062-02n
Received: March 2, 2004
Institution: Monsanto
Interstate destination: CO MN MO ND SD
Release destination: ND
Applicant #: 2004-363XRAB
Effective: April 1, 2004
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

__X__ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: _____

Signature: (b) (6), (b) (7)(C)

Date: MARCH 16, 2004

State: COLORADO

Rptloc01/R4

OR120018_BR_011377
MAR 16 2004

Faxed 3/15/04

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

March 5, 2004

Dear Dr. Hanks:

Enclosed is notification 04-062-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-062-02n	Applicant #:	2004-363XRAB
Received:	March 2, 2004	Effective:	April 1, 2004
Institution:	Monsanto	Recipient:	Wheat

Interstate destination: CO MN MO ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. movement only

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 3-15-04

State: MN

Rptloc01/R4

MAR 15 2004

OR120018_BR_011378

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 5, 2004

Dear Mr. Nelson:

Enclosed is notification 04-062-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	04-062-02n	Applicant #:	2004-363XRAB
Received:	March 2, 2004	Effective:	April 1, 2004
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	CO MN MO ND SD		
Release destination:	ND		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. ATTACHMENT

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State Official: David R Nelson

Signature: (b) (6), (b) (7)(C)

Date: 3-16-04

State: ND

Rptloc01/R4

OR120018_BR_011379

MAR 17 2004

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

March 5, 2004

Dear Mr. Fridley:

Enclosed is notification 04-062-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-062-02n Applicant #: 2004-363XRAB
Received: March 2, 2004 Effective: April 1, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CO MN MO ND SD
Release destination: ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO



STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 3/12/04

State: South Dakota

Rptloc01/R4

MAR 15 2004

OR120018_BR_011380

April 6, 2004

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after April 6, 2004.**

Interstate movement and Release
Notification no. 04-062-02n (2004-363XRAB)
Regulated article - Wheat
Destinations - Colorado, Minnesota, Missouri, North Dakota, South Dakota

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of North Dakota has (attached) conditions.

In addition, the State of Minnesota concur for movement only.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
M. Yergert, Colorado Dept. of Agric., Lakewood, CO
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 04-062-02n

OR120018_BR_011381

AGRICULTURE COMMISSIONER
ROGER JOHNSON

PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: Mary Jackson
Biotechnology Program Operations – Permit Unit
USDA APHIS
4700 River Road
Riverdale MD 27037

FROM: David R. Nelson (b) (6), (b) (7)(C)
DATE: March 16, 2004
RE: Supplemental Conditions for Release of Wheat

Bp Number	Applicant Number	Institution
04-015-13n	2004-39XRAB	Monsanto
04-021-05n	2004-36XRAB	Monsanto
04-035-06n	2004-225XRAB	Monsanto
04-062-02n	2004-363XRAB	Monsanto
04-064-07n	2004-375XRAB	Monsanto
04-063-04n	SYN2004-107	Syngenta

The North Dakota Department of Agriculture concurs with the above mentioned notifications for transgenic wheat and suggests the following supplemental conditions. Thank you for the opportunity to comment.

North Dakota Supplemental Conditions 2004

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.

2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.

3. Because of the possibility of volunteers:

   - Wheat , or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.

   - If a transgenic wheat plot is harvested with a commercial combine (other than a small plot combine), then wheat or crops that would make locating or controlling volunteer wheat difficult (e.g, other small grains), should not be grown with the field trial area nor within 50 meters of the field trial area during the subsequent two growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.

- Consultation should occur with the North Dakota Agriculture Experiment Station Director and the NDSU Seedstocks Director prior to planting to assure that isolation of at least 330 feet from Foundation Seedstock production and other significant ND Agricultural Experiment Station plantings is maintained.

Confirmation Report-Memory Send

Time : Apr-12-04 04:38pm
Tel line 1 :
Tel line 2 :
Name :

Job number : 292
Date : Apr-12 04:36pm
To : 916367377085
Document Pages : 02
Start time : Apr-12 04:37pm
End time : Apr-12 04:38pm
Pages sent : 02
Job number : 292 *** SEND SUCCESSFUL ***

USDA United States Department of Agriculture | Animal and Plant Health Inspection Service | Biotechnology Regulatory Services | 4700 River Road, Unit 147 Riverdale, Maryland 20737-1236

April 6, 2004

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 6, 2004.

Interstate movement and Release
Notification no. 04-062-02n (2004-363XRAB)
Regulated article - Wheat
Destinations - Colorado, Minnesota, Missouri, North Dakota, South Dakota

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of North Dakota has (attached) conditions.

In addition, the State of Minnesota concur for movement only.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory officials.

Sincerely,

(b) (6), (b) (7)(C)
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
M. Yergert, Colorado Dept. of Agric., Lakewood, CO
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD

APHIS- Protecting American Agriculture | An Equal Opportunity Employer

OR120018_BR_011383

CONFIDENTIAL

2004 Wheat Field Test Report
USDA #04-062-02n Monsanto #2004-363XRAB

March 24, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State
2147320162	Cass	ND
2147320143	Adams	ND
2147310478	Ward	ND

Cass County/ND (2147320162)

Planting Date: 05/04/2004

Harvest Date: 08/31/2004

Destruct Date: 08/31/2004

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)
(b) (4)

Field Monitoring Observations for Disease Susceptibility: (b) (4)
(b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)
(b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)
(b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

OR120018_BR_011384

3/25/05

(b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

(b) (4)

Disposition of the Harvested Material: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

(b) (4)

Additional Comments: (b) (4)

(b) (4)

Adams County/ND (2147320143)

Planting Date: 04/27/2004

Harvest Date: 08/13/2004

Destruct Date: 09/22/2004

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4)

(b) (4)

Field Monitoring Observations for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

(b) (4)

OR120018_BR_011385

(b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

(b) (4)

Disposition of the Harvested Material: (b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

(b) (4)

Ward County/ND (2147310478)

Planting Date: 04/27/2004

Destruct Date: 07/01/2004

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4)

(b) (4)

Field Monitoring Observations for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

(b) (4)

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

(b) (4)

Additional Comments: (b) (4)

OR120018_BR_011386

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943#44 (lOth Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011387

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

OR120018_BR_011388

CBI-DELETED

2004 Wheat Field Test Report
USDA #04-062-02n Monsanto #2004-363XRAB

March 24, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State
2147320162	Cass	ND
2147320143	Adams	ND
2147310478	Ward	ND

Cass County/ND (2147320162)

Planting Date: 05/04/2004

Harvest Date: 08/31/2004

Destruct Date: 08/31/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

Adams County/ND (2147320143)

OR120018_BR_011389

Planting Date: 04/27/2004

Harvest Date: 08/13/2004

Destruct Date: 09/22/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Ward County/ND (2147310478)

Planting Date: 04/27/2004

Destruct Date: 07/01/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

OR120018_BR_011390

3/05/04 3:13 pm Notification Tracking Sheet

==========
Bp number: 04-064-07n
==========

App number: 2004-375XRAB
Received: 3/04/04
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 4/03/04
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State/Zip: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 636-737-7085

Begin movement: 4/02/04
End movement: 4/02/05
Begin release: 4/02/04
End release: 4/02/05
Acre: 10.00
CBI status: CBI

		Initial	Date
1.	[✓] Assign Bp number and initial data entry	[ajd]	[3/9/04]
2.	[✓] Review by biotechnologist	[MPK]*	[3/10/04]*
3.	[✓] Letter of notification to State Fed-ex	[KLW]	[3/12/04]*
4.	[ ] State response		

	O/d	Loc	Site Reg		
Interstate	*Dest*	CA	*WR*	[ ]	[ ]
Interstate	*Dest*	HI	*WR*	[ ]	[ ]
Interstate	*Dest*	MN	*NER*	[ ]	[ ]
Interstate	*Dest*	MO	*SCR*	[ ]	[ ]
Interstate	*Dest*	MT	*WR*	[ ]	[ ]
Interstate	*Dest*	ND	*SCR*	[ ]	[ ]
Interstate	*Dest*	SD	*SCR*	[ ]	[ ]
Interstate	*Orig*	CA	*WR*		
Interstate	*Orig*	HI	*WR*		
Interstate	*Orig*	MN	*NER*		
Interstate	*Orig*	MO	*SCR*		
Interstate	*Orig*	MT	*WR*		
Interstate	*Orig*	ND	*SCR*		
Interstate	*Orig*	SD	*SCR*		
Release	*	*MT	* 1*WR	[ ]	[ ]
Release	*	*ND	* 1*SCR	[ ]	[ ]

		Initial	Date
5.	[✓] Enter genes into database	[ajd]	[3/10/04]
6.	[✓] Letter of acknowledgement/denial/withdraw	[KLW]	[4/2/04]*
7.	[✓] Enter final data into database	[KLW]	[4/15/04]
8.	[ ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

OR120018_BR_011391

9/3

MONSANTO

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-375XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

March 3, 2004

04-064-07n

1. USDA Reference Number

2. Application Reference Number 2004-375XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C) monsanto.com

4. Duration of Introduction

Interstate Movement and Release April 2, 2004 - April 2, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Oxen, Ingot, HJ-98, Alsen, McNeal, WP 936, WP 926, Conan, Other Experimental Lines

OR120018_BR_011392

Monsanto Reference ID
2004-375XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMoVa/I2 -- (b) (4) *CBI*

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011393

Monsanto Reference ID
2004-375XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to 10,000 pounds of wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
CA, HI, MN, MO, MT, ND, SD	CA, HI, MN, MO, MT, ND, SD

Ship From/Ship To:

CA

* (b) (4) Imperial County/Province, CA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) CA, (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

HI

* (b) (4) Honolulu County/Province, Oahu Island, HI (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) HI, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

]-CBI

MN

* (b) (4) Marshall County/Province, MN, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MN (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) Ramsey County/Province, MN, (b) (4) U.S.A.

OR120018_BR_011394

Monsanto Reference ID
2004-375XRAB

CONTACT: (b) (4), (b) (6), (b) (7)(C)
MN, (b) (4), (b) (6), (b) (7)(C) U.S.A. (b) (4), (b) (6), (b) (7)(C)

]-CBI

MO

* (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

MT

* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7) USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) Roosevelt County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) Gallatin County/Province, MT, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MT, (b) (4), (b) (6), (b) (7) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

ND

* (b) (4) McHenry County/Province, ND (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) ND, (b) (4), (b) (6), (b) (7) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

OR120018_BR_011395

Monsanto Reference ID
2004-375XRAB

*[(b) (4), (b) (6), (b) (7)(C) McHenry County/Province, ND, [redacted] USA

CONTACT [(b) (4), (b) (6), (b) (7)(C) ND, [redacted] USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ND, [redacted] USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) Cass County/Province, ND, (b) (4) USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) ND [redacted] USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

SD

*[(b) (4) Brookings County/Province, SD, (b) (4) USA

CONTACT: [(b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) SD, [redacted] USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

OR120018_BR_011396

Monsanto Reference ID
2004-375XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT(1), ND(1)

MT

[redacted] Roosevelt County/Province, MT, [redacted] USA, 5 acres. (2147320364)

RESPONSIBLE PERSON/RESEARCHER: [redacted]

]-CBI

ND

[redacted] McHenry County/Province, ND [redacted] USA, 5 acres. (2147308258)

RESPONSIBLE PERSON/RESEARCHER: [redacted]

]-CBI

OR120018_BR_011397

MONSANTO

CONFIDENTIAL

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-375XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 3, 2004

OR120018_BR_011398

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S. , 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982). Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-375XRAB

Permit Unit

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

March 3, 2004

04-064-07n

1. USDA Reference Number

2. Application Reference Number 2004-375XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)monsanto.com

4. Duration of Introduction

Interstate Movement and Release April 2, 2004 - April 2, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Oxen, Ingot, HJ-98, Alsen, McNeal, WP 936, WP 926, Conan, Other Experimental Lines

OR120018_BR_011402

CBI-DELETED

Monsanto Reference ID
2004-375XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011403

Monsanto Reference ID
2004-375XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to 10,000 pounds of wheat seed to and from each location.

ORIGIN:

CA, HI, MN, MO, MT, ND, SD

DESTINATION:

CA, HI, MN, MO, MT, ND, SD

Ship From/Ship To:

CA

[CBI Deleted] -- *Imperial County/Province, CA, USA

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Roosevelt County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

[CBI Deleted] -- *McHenry County/Province, ND, USA

OR120018_BR_011404

CBI-DELETED

Monsanto Reference ID
2004-375XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

OR120018_BR_011405

CBI-DELETED

Monsanto Reference ID
2004-375XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT(1), ND(1)

MT

[CBI Deleted] -- Roosevelt County/Province, MT, USA, 5 acres.

ND

[CBI Deleted] -- McHenry County/Province, ND, USA, 5 acres.

OR120018_BR_011406

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-375XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 3, 2004

OR120018_BR_011407

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-375XRAB

Permit Unit

March 3, 2004

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

04-064-07n

1. USDA Reference Number

2. Application Reference Number 2004-375XRAB

3. Application/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 636/737-7085

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

700 Chesterfield Parkway West

Chesterfield MO 63017

4. Duration of Introduction

Interstate Movement and Release April 2, 2004 - April 2, 2005

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Oxen, Ingot, HJ-98, Alsen, McNeal, WP 936, WP 926, Conan, Other Experimental Lines

OR120018_BR_011408

CBI-DELETED

Monsanto Reference ID
2004-375XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011409

CBI-DELETED

Monsanto Reference ID
2004-375XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

10,000 pounds. Ship up to 10,000 pounds of wheat seed to and from each location.

ORIGIN:

CA, HI, MN, MO, MT, ND, SD

DESTINATION:

CA, HI, MN, MO, MT, ND, SD

Ship From/Ship To:

CA

[CBI Deleted] -- *Imperial County/Province, CA, USA

HI

[CBI Deleted] -- *Honolulu County/Province, HI, U.S.A.

MN

[CBI Deleted] -- *Marshall County/Province, MN, USA

[CBI Deleted] -- *Ramsey County/Province, MN, U.S.A.

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

MT

[CBI Deleted] -- *Gallatin County/Province, MT, USA

[CBI Deleted] -- *Roosevelt County/Province, MT, USA

[CBI Deleted] -- *Gallatin County/Province, MT, USA

ND

[CBI Deleted] -- *McHenry County/Province, ND, USA

[CBI Deleted] -- *McHenry County/Province, ND, USA

OR120018_BR_011410

CBI-DELETED

Monsanto Reference ID
2004-375XRAB

[CBI Deleted] -- *Cass County/Province, ND, USA

[CBI Deleted] -- *Cass County/Province, ND, USA

SD

[CBI Deleted] -- *Brookings County/Province, SD, USA

OR120018_BR_011411

CBI-DELETED

Monsanto Reference ID
2004-375XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

MT(1), ND(1)

MT

[CBI Deleted] -- Roosevelt County/Province, MT, USA, 5 acres.

ND

[CBI Deleted] -- McHenry County/Province, ND, USA, 5 acres.

OR120018_BR_011412

MONSANTO

CBI-DELETED

MONSANTO COMPANY
700 CHESTERFIELD PKWY WEST
CHESTERFIELD, MISSOURI 63017
http://www.monsanto.com

Monsanto Reference ID
2004-375XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 3, 2004

OR120018_BR_011413

file copy

Mr. Stephen Brown
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

March 5, 2004

Dear Mr. Brown:

Enclosed is notification 04-064-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-064-07n Applicant #: 2004-375XRAB
Received: March 4, 2004 Effective: April 3, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CA HI MN MO MT ND SD
Release destination: MT ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011414

file copy

Dr. Neil Reimer, Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
1849 Auiki Street
Honolulu, HI 96819-3100

March 5, 2004

Dear Dr. Reimer:

Enclosed is notification 04-064-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-064-07n Applicant #: 2004-375XRAB
Received: March 4, 2004 Effective: April 3, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CA HI MN MO MT ND SD
Release destination: MT ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011415

file copy

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

March 5, 2004

Dear Dr. Hanks:

Enclosed is notification 04-064-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-064-07n Applicant #: 2004-375XRAB
Received: March 4, 2004 Effective: April 3, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CA HI MN MO MT ND SD
Release destination: MT ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011416

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

March 5, 2004

Dear Mr. Brown:

Enclosed is notification 04-064-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Ep number 04-064-07n Applicant #: 2004-375XRAB
Received: March 4, 2004 Effective: April 3, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CA HI MN MO MT ND SD
Release destination: MT ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

file copy

Ms. Lori Witham
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

March 5, 2004

Dear Ms. Witham:

Enclosed is notification 04-064-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-064-07n Applicant #: 2004-375XRAB
Received: March 4, 2004 Effective: April 3, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CA HI MN MO MT ND SD
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Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

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Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011418

file copy

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 5, 2004

Dear Mr. Nelson:

Enclosed is notification 04-064-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-064-07n Applicant #: 2004-375XRAB
Received: March 4, 2004 Effective: April 3, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CA HI MN MO MT ND SD
Release destination: MT ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011419

file copy

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

March 5, 2004

Dear Mr. Fridley:

Enclosed is notification 04-064-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-064-07n Applicant #: 2004-375XRAB
Received: March 4, 2004 Effective: April 3, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CA HI MN MO MT ND SD
Release destination: MT ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011420

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Stephen Brown
California Department of Food and Agriculture
1220 N Street - Rm A-372
Sacramento, CA 95814

March 5, 2004

Dear Mr. Brown:

Enclosed is notification 04-064-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-064-07n Applicant #: 2004-375XRAB
Received: March 4, 2004 Effective: April 3, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CA HI MN MO MT ND SD
Release destination: MT ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

__X__ State concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: /S/ Stephen S. Brown (916) 654-1017

Signature: (b) (6), (b) (7)(C)

Date: March 16, 2004

State: California

Rptloc01/R4

OR120018_BR_011421

MAR 16 2004

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road. Unit 147
Riverdale, Maryland
20737-1236

RECEIVED
MAR 15 2004
04-064-057
PLANT QUARANTINE BRANCH

March 5, 2004

Dr. Neil Reimer, Manager
Plant Quarantine Branch
Hawaii Department of Agriculture
1849 Auiki Street
Honolulu, HI 96819-3100

Dear Dr. Reimer:

Enclosed is notification 04-064-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-064-07n
Received: March 4, 2004
Institution: Monsanto
Interstate destination: CA HI MN MO MT ND SD
Release destination: MT ND
Applicant #: 2004-375XRAB
Effective: April 3, 2004
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. Please notify Ms. Carol Okada, Hawaii Department of Agriculture, 1849 Auiki Street, Honolulu, HI 96819.

____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Carol L. Okada

Signature: (b) (6), (b) (7)(C)

Date: 24 March 2004

State: Hawaii

Rptloc01/R4

*The movement of wheat seed into Hawaii is unrestricted. Wheat plantlets and green tissue require state permits. Please call Carol Okada at (808) 832-0580 for information on this type of movement into Hawaii.

OR120018_BR_011422

MAR 24 2004

03-24-04 09:53pm From-PLANT QUARANTINE HNL 8088320584 T-460 P.01/02 F-666

Paper 3-11-04

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

March 5, 2004

Dr. Mary J. Hanks, Biotechnologist
Plant Industry Division
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

Dear Dr. Hanks:

Enclosed is notification 04-064-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-064-07n Applicant #: 2004-375XRAB
Received: March 4, 2004 Effective: April 3, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CA HI MN MO MT ND SD
Release destination: MT ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Holman, PPQ, Raleigh, NC

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. movement only

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Mary J. Hanks

Signature: (b) (6), (b) (7)(C)

Date: 3-19-04

State: MN

Rptloc01/R4

OR120018_BR_011423

MAR 19 2004

United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

March 5, 2004

Ms. Lori Witham
Agriculture Sciences Division
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620-0201

Dear Ms. Witham:

Enclosed is notification 04-064-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-064-07n Applicant #: 2004-375XRAB
Received: March 4, 2004 Effective: April 3, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CA HI MN MO MT ND SD
Release destination: MT ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

✓ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Lori Witham

Signature (b) (6), (b) (7)(C)

Date: 3/15/04

State: Montana

Rptloc01/R4

OR120018_BR_011424
MAR 15 2004

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. David R. Nelson, State Entomologist
North Dakota Department of Agriculture
600 East Boulevard, 6th Floor
Bismarck, ND 58505-0020

March 5, 2004

Dear Mr. Nelson:

Enclosed is notification 04-064-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-064-07n Applicant #: 2004-375XRAB
Received: March 4, 2004 Effective: April 3, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CA HI MN MO MT ND SD
Release destination: MT ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

X State concurs with APHIS determination. Attachment

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: David R Nelson

Signature: (b) (6), (b) (7)(C)

Date: 3-16-04

State: ND

Rptloc01/R4

OR120018_BR_011425

MAR 17 2004

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Kevin Fridley
Division of Agricultural Services
South Dakota Department of Agriculture
Foss Building-523 East Capitol
Pierre, SD 57501-3182

March 5, 2004

Dear Mr. Fridley:

Enclosed is notification 04-064-07n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 04-064-07n Applicant #: 2004-375XRAB
Received: March 4, 2004 Effective: April 3, 2004
Institution: Monsanto Recipient: Wheat
Interstate destination: CA HI MN MO MT ND SD
Release destination: MT ND

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimillie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

MAR 2004 RECEIVED S.D. DEPT. OF AGRICULTURE

STATE RESPONSE TO NOTIFICATION

__X__ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: Kevin Fridley

Signature: (b) (6), (b) (7)(C)

Date: 3/15/04

State: South Dakota

Rptloc01/R4

OR120018_BR_011426
MAR 15 2004

April 2, 2004

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and **may be executed according to 7 CFR 340.3(c), effective on or after April 3, 2004.**

Interstate movement and Release
Notification no. 04-064-07n (2004-375XRAB)
Regulated article - Wheat
Destinations - California, Hawaii, Minnesota, Missouri, Montana, North Dakota, South Dakota

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

The State of North Dakota has (attached) conditions.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 1849 Auiki Street, Honolulu, Hawaii 96819, upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
S. Brown, California Dept. of Food and Agric., Sacramento, CA
N. Reimer, Hawaii Dept. of Agric., Honolulu, HI
M. Hanks, Minnesota Dept. of Agric., St. Paul, MN
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
L. Witham, Montana Dept. of Agric., Helena, MT
D. Nelson, North Dakota Dept. of Agric., Bismarck, ND
K. Fridley, South Dakota Dept. of Agric., Pierre, SD
File number 04-064-07n

OR120018_BR_011428

California Quarantine Requirements
USDA/APHIS Biotechnology Notification No. 04-064-07N

1. Shipments of wheat seed to California from all states and districts of the United States east of and including Minnesota, Iowa, Missouri, Arkansas and Louisiana, and parts of Montana and North Dakota shall meet the requirements of Section 3277, Title 3, California Code of Regulations, Cereal Leaf Beetle.

2. Permittee shall notify the Office of the Imperial County Agricultural Commissioner upon arrival of shipments (760) 482-4314.

OR120018_BR_011429

AGRICULTURE COMMISSIONER
ROGER JOHNSON

PHONE (701) 328-2231
(800) 242-7535
FAX (701) 328-4567

DEPARTMENT OF AGRICULTURE
State of North Dakota
600 E. Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020

TO: Mary Jackson
Biotechnology Program Operations – Permit Unit
USDA APHIS
4700 River Road
Riverdale MD 27037

FROM: David R. Nelson (b) (6), (b) (7)(C)
DATE: March 16, 2004
RE: Supplemental Conditions for Release of Wheat

Bp Number	Applicant Number	Institution
04-015-13n	2004-39XRAB	Monsanto
04-021-05n	2004-36XRAB	Monsanto
04-035-06n	2004-225XRAB	Monsanto
04-062-02n	2004-363XRAB	Monsanto
04-064-07n	2004-375XRAB	Monsanto
04-063-04n	SYN2004-107	Syngenta

The North Dakota Department of Agriculture concurs with the above mentioned notifications for transgenic wheat and suggests the following supplemental conditions. Thank you for the opportunity to comment.

North Dakota Supplemental Conditions 2004

1. Isolation from wheat that will be harvested for use as seed should be at least 330 feet. This includes all classes of certified wheat seed as well as any wheat grain that may be used as common seed.

2. Isolation from any wheat that will be harvested for grain should be at least 100 feet.

3. Because of the possibility of volunteers:

   - Wheat , or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown within the field trial area nor within 33 feet of the field trial area during the subsequent two (2) growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.

   - If a transgenic wheat plot is harvested with a commercial combine (other than a small plot combine), then wheat or crops that would make locating or controlling volunteer wheat difficult (e.g. other small grains), should not be grown with the field trial area nor within 50 meters of the field trial area during the subsequent two growing seasons and any wheat volunteers appearing within this area should be destroyed prior to flowering.

- Consultation should occur with the North Dakota Agriculture Experiment Station Director and the NDSU Seedstocks Director prior to planting to assure that isolation of at least 330 feet from Foundation Seedstock production and other significant ND Agricultural Experiment Station plantings is maintained.

Confirmation Report–Memory Send

Time : Apr-06-04 03:30pm
Tel line 1 :
Tel line 2 :
Name :

Job number	:	166
Date	:	Apr-06 03:28pm
To	:	916367377085
Document Pages	:	04
Start time	:	Apr-06 03:29pm
End time	:	Apr-06 03:30pm
Pages sent	:	04

Job number : 166 *** SEND SUCCESSFUL ***

USDA United States Department of Agriculture | Animal and Plant Health Inspection Service | Biotechnology Regulatory Services | 4700 River Road, Unit 147 Riverdale, Maryland 20737-1236

April 2, 2004

(b) (6), (b) (7)(C)
[redacted]
700 Chesterfield Pkwy W
Chesterfield, MO 63017

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c), effective on or after April 3, 2004.

Interstate movement and Release
Notification no. 04-064-07n (2004-375XRAB)
Regulated article - Wheat
Destinations - California, Hawaii, Minnesota, Missouri, Montana, North Dakota, South Dakota

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. All packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

The State of California concurs with APHIS determination; provided, all applicable quarantine requirements are met (see attached).

The State of North Dakota has (attached) conditions.

In addition, the State of Hawaii has requested that you adhere to the following requirement:

1. Notify State Agricultural Official, Ms. Carol Okada, Hawaii Department of Agriculture, 1849 Auiki Street, Honolulu, Hawaii 96819, upon arrival.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

(b) (6), (b) (7)(C)
[redacted]
Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

APHIS- Protecting American Agriculture | An Equal Opportunity Employer

OR120018_BR_011431

CONFIDENTIAL

2004 Wheat Field Test Report
USDA #04-064-07n Monsanto #2004-375XRAB

March 9, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State
2147320364	Roosevelt	MT
2147308258	McHenry	ND

Roosevelt County/MT (2147320364)

Planting Date: 05/01/2004

Harvest Date: 08/19/2004

Vector Constructs/Line Numbers Planted: (b) (4) - CBI

Purpose of Field Trial: (b) (4)

Field Monitoring Observations for Disease Susceptibility: (b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

OR120018_BR_011432

3/10/05

Field Monitoring Observations for Plant Stand: (b) (4)

(b) (4)

Disposition of the Harvested Material: (b) (4)

(b) (4)

McHenry County/ND (2147308258)

Planting Date: 04/30/2004

Harvest Date: 09/07/2004

Destruct Date: 09/07/2004

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

(b) (4)

Field Monitoring Observations for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Stand: (b) (4)

(b) (4)

Disposition of the Harvested Material: (b) (4)
CBI

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

(b) (4)

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943#44 (lOth Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011434

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

OR120018_BR_011435

CBI-DELETED

2004 Wheat Field Test Report
USDA #04-064-07n Monsanto #2004-375XRAB

March 9, 2005

Biotech Field Compliance Team
Monsanto Company

Location	County	State
2147320364	Roosevelt	MT
2147308258	McHenry	ND

Roosevelt County/MT (2147320364)

Planting Date: 05/01/2004

Harvest Date: 08/19/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

McHenry County/ND (2147308258)

Planting Date: 04/30/2004

Harvest Date: 09/07/2004

Destruct Date: 09/07/2004

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

OR120018_BR_011436

3/11/05

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

OR120018_BR_011437

3/09/05 8:43 am Notification Tracking Sheet

==========
Bp number: 05-067-02n
==========

App number: 2005-297XRAB
Received: 3/08/05
Institution: Monsanto
Recipient: Wheat
Status: Pending
Effective date: 4/07/05
Phenotype: HT - Glyphosate tolerant
Comments:
Resp person:
Parsed name:
Address1: Monsanto Company
Address2: 800 Lindberg Blvd.
Address3:
Address4:
City/State/Zip: St. Louis, MO 63167
Telephone: (b) (6), (b) (7)(C)

Begin movement: 4/06/05
End movement: 4/06/06
Begin release: 4/06/05
End release: 4/06/06
Acre: 2.00
CBI status: CBI

(b) (6), (b) (7)(C)

Fax: 314-694-7086

		Initial	Date
1.	[✓] Assign Bp number and initial data entry	[ajd]	[3/9/05]
2.	[✓] Review by biotechnologist	[jmc]*	[3/10/05]*
3.	[✓] Letter of notification to State Fed-ex	[KLD]	[3/15/05]*
4.	[ ] State response		

	O/d	Loc	Site	Reg		
Interstate	*Dest*	MO	*	SCR	[ ]	[ ]
Interstate	*Dest*	WA	*	WR	[ ]	[ ]
Interstate	*Orig*	MO	*	SCR		
Interstate	*Orig*	WA	*	WR		
Release	*	WA	*	2*WR	[ ]	[ ]

5.	[✓] Enter genes into database	[ajd]	[3/10/05]
6.	[✓] Letter of acknowledgement/denial/withdraw	[KLD]	[4/4/05]*
7.	[✓] Enter final data into database	[KLD]	[4/7/05]
8.	[ ] If deny, reason: Address incomplete, Signature mismatch, Ph category, Phenotype, Gene, Donor, Marker, Does not qualify		

4/2

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Monsanto Reference ID
2005-297XRAB

Permit Unit

March 7, 2005

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

05-067-02n

1. USDA Reference Number

2. Applicant Reference Number 2005-297XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 314/694-7086

Monsanto Company

Email (b) (6), (b) (7)(C)@monsanto.com

800 Lindberg Blvd.

St. Louis MO 63167

4. Duration of Introduction

Interstate Movement and Release April 6, 2005 - April 6, 2006

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

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Monsanto Reference ID
2005-297XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMoVa/I2 -- [redacted] (b) (4) *CBI*

(b) (4)

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

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2005-297XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

Ship up to 10000 pounds wheat seed to and from each location.

ORIGIN:	**DESTINATION:**
MO, WA	MO, WA

Ship From/Ship To:

MO

* (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) St. Louis County/Province, MO (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) USA (b) (4), (b) (6), (b) (7)(C)

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]-CBI

*[(b) (4) St. Louis County/Province, MO, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) St. Louis County/Province, MO (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
U.S.A., (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) St. Louis County/Province, MO (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO,
(b) (4), (b) (6), (b) (7)(C) U.S.A., (b) (4), (b) (6), (b) (7)(C)

]-CBI

*[(b) (4) St. Louis County/Province, MO, (b) (4)
U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) MO, (b) (4), (b) (6), (b) (7)(C)
U.S.A., (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) St. Louis County/Province, MO,
(b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) MO (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

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* (b) (4) St. Louis County/Province, MO, (b) (4) U.S.A.

CONTACT: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) MO (b) (4), (b) (6), (b) (7) USA (b) (4), (b) (6), (b) (7)(C)

]-CBI

WA

* (b) (4) (b) (4) Walla Walla County/Province, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA, (b) (4), (b) (6), (b) (7) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

* (b) (4) Grant County/Province, WA, (b) (4) USA

CONTACT: (b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

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Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA(2)

WA

[(b) (4) (b) (4) Walla Walla County/Province, WA, (b) (4) USA, 1 acres. (2147319467)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

[(b) (4) Grant County/Province, WA, (b) (4) USA, 1 acres. (519)

RESPONSIBLE PERSON/RESEARCHER: (b) (4), (b) (6), (b) (7)(C) (b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C) USA, (b) (4), (b) (6), (b) (7)(C)

]-CBI

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CONFIDENTIAL

Monsanto Reference ID
2005-297XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 7, 2005

OR120018_BR_011445

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene descriptions (referred to as vector components) category includes the names and information about genes and their express traits, promoters and terminators (stop signal).

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. Section 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974); Gulf & Western Industries, Inc. v. U.S. , 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982). Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v Dept. of Health & Human Services, 907 F.2d 936, 943-44 (10th Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (10th Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at 213, 1216-1218 (D.C.Cir.1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C.1990). Specific justifications for treating information in these two categories as CBI are provided below*.

*In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

Gene Description

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of agricultural biotechnology since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, project documents for the various research facilities.

The uniqueness of this product lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promoter region, the gene for the expression of the trait and the terminator. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include, but are not limited to companies such: Novartis, Agrevo, Xeneca and DuPoint.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

Names And Information About Genes, Promoters, Terminators And Expressed Traits

The release of information about the genes, promoters and terminators in the vectors will directly provide competitors with the knowledge of the precise genetic sequence that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for some of the products at issue in this matter are pending, but have not been issued. Information on the expressed trait of the genes is tantamount to

providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

Identity and Characteristics of Donor Organisms

A donor organism is not claims as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms have been incorporated in the description for each of the components of the vector for the product subject to this justification have been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identity of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Identification Of Physical Site And Release Location

The identity of the physical site and release locations have been claimed confidential by Monsanto. Disclosure of this information would reveal precise shipping locations and field testing facilities to environmental activists. The destruction of this valuable technology could substantially put at risk the safety of Monsanto's cooperators and jeopardize the expense and time intensive effort by Monsanto.

Identification Of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as **[CBI]** and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled **[CBI-Deleted]** and that document labeled as CBI-Deleted.

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St. Lous, Missouri 63167
http://www.monsanto.com

CBI-DELETED

Monsanto Reference ID
2005-297XRAB

Permit Unit

March 7, 2005

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

05-067-02n

1. USDA Reference Number

2. Applicant Reference Number 2005-297XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 314/694-7086

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

800 Lindberg Blvd.

St. Louis MO 63167

4. Duration of Introduction

Interstate Movement and Release April 6, 2005 - April 6, 2006

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

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CBI-DELETED

Monsanto Reference ID
2005-297XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011450

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CBI-DELETED

Monsanto Reference ID
2005-297XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

Ship up to 10000 pounds wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From/Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

[CBI Deleted] -- *St. Louis County/Province, MO, USA

[CBI Deleted] -- *St. Louis County/Province, MO, USA

[CBI Deleted] -- *St. Louis County/Province, MO, USA

[CBI Deleted] -- *St. Louis County/Province, MO, USA

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

[CBI Deleted] -- *St. Louis County/Province, MO, USA

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

[CBI Deleted] -- *Grant County/Province, WA, USA

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800 North Lindbergh Blvd.
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http://www.monsanto.com

CBI-DELETED

Monsanto Reference ID
2005-297XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA(2)

WA

[CBI Deleted] -- Walla Walla County/Province, WA, USA, 1 acres.

[CBI Deleted] -- Grant County/Province, WA, USA, 1 acres.

OR120018_BR_011452

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800 North Lindbergh Blvd.
St. Lous, Missouri 63167
http://www.monsanto.com

CBI-DELETED

Monsanto Reference ID
2005-297XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 7, 2005

OR120018_BR_011453

MONSANTO imagine™

Monsanto Company
800 North Lindbergh Blvd.
St. Lous, Missouri 63167
http://www.monsanto.com

CBI-DELETED

Monsanto Reference ID
2005-297XRAB

Permit Unit

March 7, 2005

USDA, APHIS, PPQ, BSS

4700 River Rd.

Riverdale, MD 27037

05-067-02n

1. USDA Reference Number

2. Applicant Reference Number 2005-297XRAB

3. Applicant/Responsible Party

(b) (6), (b) (7)(C)

Phone (b) (6), (b) (7)(C)

Fax 314/694-7086

Email (b) (6), (b) (7)(C)@monsanto.com

Monsanto Company

800 Lindberg Blvd.

St. Louis MO 63167

4. Duration of Introduction

Interstate Movement and Release April 6, 2005 - April 6, 2006

5. Recipient

Wheat, Triticum aestivum

6. Regulated Article

Phenotypic Category: HT

Phenotype: Glyphosate tolerant

Cultivar(s)/Variety(ies): Bobwhite

OR120018_BR_011454

MONSANTO
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Monsanto Company
800 North Lindbergh Blvd.
St. Lous, Missouri 63167
http://www.monsanto.com

CBI-DELETED

Monsanto Reference ID
2005-297XRAB

designation of transformed line: 33391

Constructs: PV-TXGT10

GENE OF INTEREST

Promoter: CMP3/I5 -- A fragment containing the promoter and 5' intron from the rice (Oryza sativa) actin 1 gene.

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

GENE OF INTEREST

Promoter: CMoVa/I2 -- [CBI Deleted] ***CBI***

Gene: CTP2-CP4 -- A gene fusion composed of the N-terminal chloroplast transit peptide sequence from the Arabidopsis thaliana EPSPS gene (CTP2), and the C-terminal 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an Agrobacterium species, strain CP4.

Transcription termination sequence: NOS 3' -- A 3' non-translated region of the nopaline synthase gene of Agrobacterium tumefaciens T-DNA.

OR120018_BR_011455

Monsanto Company
800 North Lindbergh Blvd.
St. Lous, Missouri 63167
http://www.monsanto.com

CBI-DELETED

Monsanto Reference ID
2005-297XRAB

7. Mode of Transformation

PV-TXGT10	GENE OF INTEREST	CMP3/I5	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens
PV-TXGT10	GENE OF INTEREST	CMoVa/I2	CTP2-CP4	NOS 3'	Disarmed Agrobacterium tume-faciens

8. Introduction Interstate Movement and Release

Ship up to 10000 pounds wheat seed to and from each location.

ORIGIN:

MO, WA

DESTINATION:

MO, WA

Ship From/Ship To:

MO

[CBI Deleted] -- *St. Louis County/Province, MO, USA

[CBI Deleted] -- *St. Louis County/Province, MO, USA

[CBI Deleted] -- *St. Louis County/Province, MO, USA

[CBI Deleted] -- *St. Louis County/Province, MO, USA

[CBI Deleted] -- *St. Louis County/Province, MO, USA

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

[CBI Deleted] -- *St. Louis County/Province, MO, USA

[CBI Deleted] -- *St. Louis County/Province, MO, U.S.A.

WA

[CBI Deleted] -- *Walla Walla County/Province, WA, USA

[CBI Deleted] -- *Grant County/Province, WA, USA

OR120018_BR_011456

MONSANTO imagine™

Monsanto Company
800 North Lindbergh Blvd.
St. Lous, Missouri 63167
http://www.monsanto.com

CBI-DELETED

Monsanto Reference ID
2005-297XRAB

Release Site:

NUMBER OF STATES/TERRITORIES AND SITES:

WA(2)

WA

[CBI Deleted] -- Walla Walla County/Province, WA, USA, 1 acres.

[CBI Deleted] -- Grant County/Province, WA, USA, 1 acres.

OR120018_BR_011457

MONSANTO
imagine™

Monsanto Company
800 North Lindbergh Blvd.
St. Lous, Missouri 63167
http://www.monsanto.com

CBI-DELETED

Monsanto Reference ID
2005-297XRAB

9. Certification

I certify that the regulated article will be introduced in accordance with the eligibility criteria and the performance standards set forth in 7 CFR 340.3. The above information is true to the best of our knowledge. If there are any changes, we will contact APHIS.

(b) (6), (b) (7)(C)

Monsanto Company

March 7, 2005

OR120018_BR_011458

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

March 9, 2005

Dear Mr. Brown:

Enclosed is notification 05-067-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	05-067-02n	Applicant #:	2005-297XRAB
Received:	March 8, 2005	Due Date:	April 7, 2005
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011459

Mr. Michael Brown
Plant Industries Division
Missouri Department of Agriculture
1616 Missouri Boulevard
Jefferson City, MO 65102

Inspection Copy

March 9, 2005

Dear Mr. Brown:

Enclosed is notification 05-067-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	05-067-02n	Applicant #:	2005-297XRAB
Received:	March 8, 2005	Due Date:	April 7, 2005
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Fort Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011460

Mr. Thomas L. Wessels, Plant Services Program Manager March 9, 2005
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

Dear Mr. Wessels:

Enclosed is notification 05-067-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number	05-067-02n	Applicant #:	2005-297XRAB
Received:	March 8, 2005	Due Date:	April 7, 2005
Institution:	Monsanto	Recipient:	Wheat
Interstate destination:	MO WA		
Release destination:	WA		

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

_____State concurs with APHIS determination.

_____State DOES NOT CONCUR and offers the following reasons:

Name of State official:_____

Signature:_____

Date:_____

State:_____ Rptloc01/R4

OR120018_BR_011461

USDA United States Department of Agriculture
Animal and Plant Health Inspection Service
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

Mr. Thomas L. Wessels, Plant Services Program Manager
Laboratory Services Division
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504-2560

March 9, 2005

Dear Mr. Wessels:

Enclosed is notification 05-067-02n for your review. The information has been reviewed and it has been determined that the request meets the eligibility criteria and performance standards for notification under 7 CFR 340.3 (c).

Bp number 05-067-02n
Received: March 8, 2005
Institution: Monsanto
Interstate destination: MO WA
Release destination: WA

Applicant #: 2005-297XRAB
Due Date: April 7, 2005
Recipient: Wheat

Should you have comments, please respond either by telephone (301) 734-8443 or by facsimilie (301) 734-8910 on or before the effective date.

It is mandated under 7 CFR 340.3 (c) that APHIS provide an acknowledgement within 30 days of receipt.

Sincerely,

(b) (6), (b) (7)(C)

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Permits and Risk Assessments
Plant Protection and Quarantine

Enclosure

cc: R. Stoaks, PPQ, Ft. Collins, CO

STATE RESPONSE TO NOTIFICATION

✓ State concurs with APHIS determination.

_____ State DOES NOT CONCUR and offers the following reasons:

Name of State official: [illegible]

Signature: (b) (6), (b) (7)(C)

Date: 3/21/05

State: WA

Rptloc01/R4

MAR 21 2005

OR120018_BR_011462

NEPA/ESA Decision Document for Notification Applications

General Information	
APHIS Reference number:	Reviewer: JMC

Reviewer's Recommendation	
Approve	Deny
☑	☐

Reviewer's Evaluation of Compliance with 7 C.F.R. §340.3		
Eligibility Criteria	**Yes**	**No**
The recipient is a plant.	☑	☐
The plant is not on the list of federally-recognized noxious weed species, nor, in the case of a release, is it considered a weed in the state(s) where it will be released.	☑	☐
The introduced genetic material cannot have been derived from an animal or human pathogen.	☑	☐
The function of all introduced genetic material is known.	☑	☐
The function of any products encoded by the genetic material is known.	☑	☐
The expression of the genetic material • Does not result in the production of a substance known or likely to cause disease in humans or non-target animals, including threatened or endangered species • Does not result in plant disease • Does not result in the production of virus particles or any other infectious entity • Does not result in the production of substances known or likely to be toxic to non-target organisms, including threatened or endangered species, known or likely to feed or live on the plant • Does not result in the production of a substance intended for pharmaceutical or industrial use	☑ ☑ ☑ ☑ ☑	☐ ☐ ☐ ☐ ☐
If plant virus-derived sequences have been used: • They must be non-coding, regulatory sequences of known function OR • They must be sense or anti-sense constructs derived from plant viruses prevalent in and endemic to the area where the introduction will occur, infecting plants of the same species and which do not encode a functional noncapsid gene product responsible for cell-to-cell movement of the virus. Check here if not applicable ☐	☑	☐
The genetic material has been introduced via a method (e.g. *Agrobacterium* transformation or biolistics) that results in the stable incorporation of the foreign DNA in the plant genome.	☑	☐

Additional Comments:

The regulated article(s) described in this notification meet(s) all of the requirements set forth under 7 C.F.R. sec. 340.3(b) and is(are) therefore eligible for introduction under the notification procedure. Protocols designed to meet the performance standards as required under 7 C.F.R. sec. 340.3(c) have either been submitted with this application or have already been submitted to APHIS with a prior application. Any field testing of genetically engineered plants proposed in this notification has been deemed confined. Therefore this notification qualifies for categorical exclusion status under 7 C.F.R. sec. 372.5(c)(3)(ii) and neither an environmental assessment nor an environmental impact statement is required.

Signed: (b) (6), (b) (7)(C)

Date: 3/10/05

April 4, 2005

(b) (6), (b) (7)(C)
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c). You are authorized to initiate this movement and release from April 4, 2005, through, April 4, 2006.

Interstate movement and Release
Notification no. 05-067-02n (2005-297XRAB)
Regulated article - Wheat
Destinations - Missouri, Washington

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

Sincerely,

/S/

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:
M. Brown, Missouri Dept. of Agric., Jefferson City, MO
T. Wessels, Washington Dept. of Agric., Olympia, WA
File number 05-067-02n

TRANSMISSION VERIFICATION REPORT

TIME : 04/04/2005 15:06
NAME : BRS
FAX : 3017348910
TEL : 3017348910
SER.# : BROJ4J118682

DATE,TIME	04/04 15:05
FAX NO./NAME	913146947086
DURATION	00:00:42
PAGE(S)	04
RESULT	OK
MODE	STANDARD ECM

USDA United States Department of Agriculture

Animal and Plant Health Inspection Service

Biotechnology Regulatory Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

April 4, 2005

(b) (6), (b) (7)(C)
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

Dear (b) (6), (b) (7)(C)

Your notification request has been acknowledged and may be executed according to 7 CFR 340.3(c). You are authorized to initiate this movement and release from April 4, 2005, through, April 4, 2006.

Interstate movement and Release
Notification no. 05-067-02n (2005-297XRAB)
Regulated article - Wheat
Destinations - Missouri, Washington

This acknowledgment letter must be provided to all cooperators.

You must comply with the performance standards as stated in 7 CFR 340.3(c). You or any of your cooperators who will be involved in handling the regulated article must be prepared with a written or verbal description of the methods to be employed to meet each performance standard. In addition, all packages must be clearly labeled as to content, and notification number must be prominently displayed on package.

This acknowledgment does not authorize use of "challenge organisms" for field test.

A copy of this letter of acknowledgment will be sent to the receiving State Regulatory Officials.

OR12006_BR_01465

MONSANTO

CONFIDENTIAL

MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
http://www.monsanto.com

April 20, 2005

Mr. Juan A. Roman
Team Leader, Permitting and Notifications
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD, 20737-1237

Re: Farm Movement/Release Address Correction USDA#'s 05-021-10n (Monsanto# 2005-57XRAB) and 05-067-02n (Monsanto# 2005-297XRAB)

Dear Mr. Roman;

I am writing to inform you that the following movement and release farm address for (b) (4) (b) (4) – CBI is incorrect on approved USDA notifications 05-021-10n (Monsanto# 2005-57XRAB) and 05-067-02n (Monsanto# 2005-297XRAB).

The incorrect address is:

(b) (4) – CBI Walla Walla County/Province, WA (b) (4) USA

The correct **address** is:

(b) (4) - CBI Walla Walla County/Province, WA (b) (4) USA

If you have any questions concerning this correction, please contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

cc: R. Stoaks

MONSANTO

CBI-DELETED

MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
http://www.monsanto.com

April 20, 2005

Mr. Juan A. Roman
Team Leader, Permitting and Notifications
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD, 20737-1237

Re: Farm Movement/Release Address Correction USDA#'s 05-021-10n (Monsanto# 2005-57XRAB) and 05-067-02n (Monsanto# 2005-297XRAB)

Dear Mr. Roman;

I am writing to inform you that the following movement and release farm address for [CBI DELETED] is incorrect on approved USDA notification# 05-021-10n (Monsanto# 2005-57XRAB) and 05-067-02n (Monsanto# 2005-297XRAB).

The incorrect address is:

[CBI DELETED] Walla Walla County/Province, WA, USA

The **correct address** is:

[CBI DELETED] Walla Walla County/Province, WA, USA

If you have any questions concerning this correction, please contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

Cc: R. Stoaks

MONSANTO

MONSANTO COMPANY
800 NORTH LINDBERGH BOULEVARD
ST. LOUIS, MISSOURI 63167
PHONE (314) 694-1000
http://www.monsanto.com

CONFIDENTIAL

April 21, 2005

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notification(s):

USDA#	Monsanto#
05-067-02n	2005-297XRAB

The former name/address information is:

(b) (4)

(b) (4) Walla Walla, WA (b) (4) **- CBI**

The new name/address information is:

(b) (4)

(b) (4), Walla Walla, WA, (b) (4) **- CBI**

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

MONSANTO

MONSANTO COMPANY
800 NORTH LINDBERGH BOULEVARD
ST. LOUIS, MISSOURI 63167
PHONE (314) 694-1000
http://www.monsanto.com

CBI-DELETED

April 21, 2005

Mr. Juan A. Roman
Team Leader
Permitting and Notification
USDA, APHIS
4700 River Road, Unit 147
Riverdale, MD 20737

Dear Mr. Roman:

I would like to inform you of a change in the farm (or company) name and/or address for the approved notification(s):

USDA#	**Monsanto#**
05-067-02n	2005-297XRAB

The former name/address information is:
[CBI Deleted] - Walla Walla,WA

The new name/address information is:
[CBI Deleted] - Walla Walla, WA

If you have any questions, please contact me at (b) (6), (b) (7)(C)

Sincerely yours,

(b) (6), (b) (7)(C)

CONFIDENTIAL

2005 Wheat Field Test Report
USDA #05-067-02n Monsanto #2005-297XRAB

January 4, 2006

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
2147323675	Walla Walla	WA	
519	Grant	WA	Not Planted

Walla Walla County/WA (2147323675)

Planting Date: 04/16/2005

Harvest Date: 07/25/2005

Destruct Date: 07/25/2005

Vector Constructs/Line Numbers Planted: (b) (4)

Purpose of Field Trial: (b) (4)

Field Monitoring Observations for Disease Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Insect Susceptibility: (b) (4)

(b) (4)

Field Monitoring Observations for Plant Growth Characteristics: (b) (4)

(b) (4)

Field Monitoring Observations for Weediness Characteristics: (b) (4)

(b) (4)

OR120018_BR_011470

Field Monitoring Observations for Plant Stand: (b) (4)

(b) (4)

Disposition of the Harvested Material: (b) (4)
CBI

Method of Devitalization or Final Disposition of Plot Area after Harvesting: (b) (4)

(b) (4)

Additional Comments: (b) (4)

(b) (4)

OR1200182_BP_011471

CONFIDENTIAL BUSINESS JUSTIFICATION

The information claimed as confidential in the Field Test Report consists of field monitoring observations regarding biotechnology products under development.

Legal Background

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943#44 (lOth Cir. 1990).

Information on commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act request. The courts have been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289#291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justification for treating field monitoring observation information as CBI is provided below*.

* In a case decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 is such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011472

Field Monitoring Data as CBI

Monsanto's Field Test Reports contain information regarding Field Monitoring Observations. This includes specific observations regarding biotechnology products under development. The Field Test Report will indicate which crop is the subject of the Report and the observations provide information that can reveal the trait being tested. For instance, an observation concerning the roots of the plant is evidence that the product in testing has a trait designed to guard against rootworm.

Allowing a competitor access to such information could result in substantial competitive harm to Monsanto in that it reveals what products Monsanto is in the process of developing, the stage of development, the performance of the product under development, and an estimated time when such a product could be commercialized. A competitor could use this critical information regarding Monsanto's product pipeline to gain a competitive advantage against Monsanto. This advantage would start immediately upon the revelation of this information, in that a competitor could use this information to evaluate the timing and commercialization of its own products, to develop new competing products, and to convey information to the marketplace regarding its products compared to Monsanto's products.

In addition, the observations provide information concerning Monsanto's protocols for conducting Field Tests. Monsanto has invested substantial time and money in developing a workable system for conducting these trials and allowing others access to this information would give them an unfair advantage over Monsanto.

Identification of Items claimed as Confidential Business Information (CBI)

Items claimed as CBI indicated in the text are labeled as [CBI] and that document is labeled as Confidential. A non-confidential copy of the application is also included and the CBI information that has been deleted is enclosed in brackets labeled [CBI-Deleted] and that document labeled as CBI-Deleted.

OR120018_BR_011473

CBI-DELETED

2005 Wheat Field Test Report
USDA #05-067-02n Monsanto #2005-297XRAB

January 4, 2006

Biotech Field Compliance Team
Monsanto Company

Location	County	State	
2147323675	Walla Walla	WA	
519	Grant	WA	Not Planted

Walla Walla County/WA (2147323675)

Planting Date: 04/16/2005

Harvest Date: 07/25/2005

Destruct Date: 07/25/2005

Vector Constructs/Line Numbers Planted: [CBI-Deleted]

Purpose of Field Trial: [CBI-Deleted]

Field Monitoring Observations for Disease Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Insect Susceptibility: [CBI-Deleted]

Field Monitoring Observations for Plant Growth Characteristics: [CBI-Deleted]

Field Monitoring Observations for Weediness Characteristics: [CBI-Deleted]

Field Monitoring Observations for Plant Stand: [CBI-Deleted]

Disposition of the Harvested Material: [CBI-Deleted]

Method of Devitalization or Final Disposition of Plot Area after Harvesting: [CBI-Deleted]

Additional Comments: [CBI-Deleted]

OR120018_BR_011474

005

USDA

Worksheet 005: INSPECTION CANCELLATION WORKSHEET

A. BRS Inspection Number (BRS IN)	B. Notification, Movement, or Permit Number
06-330	05-067-02n
C. Inspector's name	**D. Inspector's phone**
George Bruno	509 353-2950
E. Name of organization contact	**F. Organization contact's title or position**
Priscilla Hunter	Monsanto compliance specialist
G. Date of cancellation	
09/05/2006	

Inspection Cancellation Procedure:

Only cancel an inspection if you can check one of these boxes:

- ☐ The regulated article will be released or planted after the due date for this inspection. (Prior to canceling the inspection, contact the BRS RBT to determine whether an extension of the inspection due date is appropriate.)
- ☑ The regulated article will not be released or planted during this growing season.
- ☐ The regulated article will never be released or planted in your state.
- ☐ The regulated article and/or the entire field trial of the regulated article has been harvested, terminated, or destroyed.
- ☐ Other. (Provide explanation in Summary of Findings.)

NOTE: Inspections canceled by BRS Headquarters do not require submission of a 005 worksheet by the inspecting officer.

Name and description of any files or documents attached to worksheet:

DO NOT RELEASE inspection worksheet, digital photographs, maps and other documents derived from your inspection to the cooperator, applicant, or other non-APHIS personnel during, or after, the inspection.

Refer anyone seeking copies of inspection related materials to the APHIS Freedom of Information Act Office at phone (301) 734-8296, fax (301) 734-5941, or 4700 River Road, Unit 50, Riverdale, MD 20737-1232.

Summary of Findings: Explain in detail the circumstances that led to cancellation of the inspection.

I spoke with Priscilla Hunter, Monsanto compliance specialist on 9/5/06 who confirmed that no wheat was planted in Washington State under permit # 05-067-02n.

Inspector's signature is not necessary.

Worksheet Submission Information:

Please fax or e-mail the completed worksheet to your BRS RBT and PPQ RPM:

Western Region

Ralph Stoaks, Ph.D.
BRS Senior Regional Biotechnologist
2150 Centre Avenue, Bldg. B-3E10
Fort Collins, CO 80526
Phone: (970) 494-7573
Fax: (970) 494-7576
Ralph.D.Stoaks@aphis.usda.gov

Stacy Scott
PPQ Regional Program Manager
2150 Centre Avenue, Bldg. B-3E16
Fort Collins, CO 80526
Phone: (970) 494-7577
Fax: (970)-494-7501
Stacy.E.Scott@aphis.usda.gov

Eastern Region

Ashima SenGupta, Ph.D.
BRS Senior Regional Biotechnologist
920 Main Campus Drive, Suite 200
Raleigh, NC 27606
Phone: (919) 855-7622
Fax: (919) 855-7323
Ashima.Sengupta@aphis.usda.gov

Susan Dublinski
PPQ Regional Program Manager
920 Main Campus Drive, Rm. 207B
Raleigh, NC 27606
Phone: (919) 855-7324
Fax: (919) 855-7395
Susan.G.Dublinski@aphis.usda.gov

94-024-01

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

January 14, 1994

Att: E.Dianne Hatmaker
Cheif, Permits Branch
Biotechnology Permits
Biotechnology, Biologics, and Environmental Protection
6505 Belcrest Rd, Suite 7
Hyattsville, MD 20782
FAX: 301-436-8910

Subject: Request for a Permit to Field Test
Marker Genes in Wheat

Dear Ms. Hatmaker:

Monsanto Agricultural Company is requesting a permit from USDA to allow wheat which has been genetically modified for the expression of marker genes to be tested in Montana.

In support of this request for a permit to allow release into the environment, please find the completed APHIS Form 2000 attached to this letter. In addition we are submitting 1 copy of the application containing the required information to support this request. This volume contains confidential business information (CBI) and is so marked on the cover and each place within the volume where the CBI occurs. As required, we are also submitting 1 copy of this same material with all CBI deleted.

This confidential information was developed by Monsanto at its own expense, has not been released to anyone not under a secrecy agreement to Monsanto and has not been published. We request that this information not be released as it has value to our competitors (domestic and foreign) in that they would be able to copy this work and unfairly compete with us causing financial loss and other harm to Monsanto.

We appreciate your attention to this matter. Should you have any questions, please feel free to contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

OR120018_BR_011477

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (IOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (IOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.[1]

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of marker genes in plants and their use in insect and virus resistant and herbicide tolerant crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

[1] In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011479

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Calgene, Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

OR120018_BR_011480

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for wheat has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

OR120018_BR_011481

ATTACHMENT
CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION
MARKER GENES IN WHEAT

Page	Category of Information	Justification
1	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011482

2	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011483

6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011484

9	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011485

12	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
13	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
13	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
14	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
14	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011486

Notice

Confidential Business Information

Some information in the attached material may be entitled to treatment as trade secret or proprietary data under Section(b)(4) of the Freedom of Information Act (FOIA) [5 U.S.C. 552(b)(4)].

Any person handling or using the attached data in any way is responsible for preventing unauthorized disclosure during possession.

Maintain this document under secure conditions.

Return to the Document Control Officer after use.

This application deals with:

Monsanto release of GE'd Wheat

identification Number:

94-024-01

The attached information is not to be published, reproduced, publicly discussed, included in response to a FOIA request, or otherwise released without the explicit written authorization of the appropriate division director or designee.

Please disqualify yourself if there is any potential Conflict of Interest

OR120018_BR_011487

CONTAINS C B I

INFORMATION SUBMITTED TO THE UNITED STATES DEPARTMENT OF AGRICULTURE IN SUPPORT OF AN APPLICATION TO FIELD TEST

TESTING OF MARKER GENES IN GENETICALLY ENGINEERED WHEAT PLANTS

93-182PR

January 14, 1994

Volume 1 of 1

Report Compiled by:
(b) (6), (b) (7)(C)

Contains Confidential Business Information (CBI)

MONSANTO AGRICULTURAL COMPANY
700 Chesterfield Parkway North • St. Louis • Missouri • 63198

OR120018_BR_011488

DISTRIBUTION

	CBI	CBI Deleted
USDA	1 Copy	1 Copy
State of Montana	-	1 Copy
(b) (6), (b) (7)(C)	1 Copy	1 Copy
REGISTRATION FILES	1 Copy	1 Copy

OR120018_BR_011489

TABLE OF CONTENTS

	page
VOLUME 1	
APHIS FORM 2000	
APHIS FORM 2000 ATTACHMENTS	1

OR120018_BR_011490

(7 U S C 151 et seq). The information will be used to determine eligibility to receive all types of permits
No permit shall be issued until this application has been approved

CONTAINS C.B.I.

See reverse side for additional information

FORM APPROVED
OMB NO 0579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

93-182R

APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

(Genetically Engineered Organisms or Products)

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

1. NAME AND ADDRESS OF APPLICANT

(b) (6), (b) (7)(C)

Monsanto Agricultural Company BB3A
700 Chesterfield Parkway North, St. Louis, MO 63198

Area Code (314 537-7488

2. PERMIT REQUESTED ("X" one)

- ☐ Limited - Interstate Movement
- ☐ Limited - Importation
- ☑ Release into the Environment
- ☐ Courtesy Permit

3. THIS REQUEST IS ("X" one)

- ☑ New
- ☐ Renewal
- ☐ Supplemental

4. TELEPHONE NUMBER

(b) (6), (b) (7)(C)

5. MEANS OF MOVEMENT

- ☑ Mail
- ☐ Baggage or Handcarried
- ☑ Common Carrier
- By whom _____

6. GIVE THE FOLLOWING *(if applicable) (if more space is needed, attach additional sheet)*

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism	See Attached			
b. Recipient Organism				
c. Vector or Vector Agent				
d. Regulated Organism or Product				
e. If product, list names of constituents				

7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS

See attached

8. DATE *(or inclusive dates of period)* **OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE**

Mar. 1, 1994 - Nov. 1, 1994

9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

See attached

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

See Attached

11. ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* **ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT**

None

12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

N/A

13. SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON	15. PRINTED NAME AND TITLE	16. DATE
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	1/13/94

FOR APHIS USE ONLY

State Notification Sent	State Review Received	Permit Issued ☐ Yes ☐ No
Date of Determination	Permit No.	No. of Permit Labels Issued
Supplemental Conditions Enclosed ☐ Yes ☐ No		
Signature of BBEP Official	Date	Expiration Date

OR120018_BR_011491

APHIS FORM 2000 (JUL 89) *Replaces PPQ Form 1001 which may be used.*

(continued on reverse)

CONTAINS C B I

	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article	X	
b	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e g , morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics)	X	
c	A detailed description of the molecular biology of the system (e g , donor-recipient-vector) which is or will be used to produce the regulated article	X	
d	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced	X	
e	A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design	X	
f	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the donor organism, recipient organism, vector or vector agent, constituent of each regulated article which is a product, and regulated article	X	
g	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e g greenhouses, laboratory, or growth chamber location, field trial location, pilot project location, production, propagation, and manufacture location, proposed sale and distribution location).	X	
	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.	X	
i	A detailed description of the proposed method of final disposition of the regulated article	X	

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

OR120018_BR_011492

CONTAINS C B I

APHIS FORM 2000 ATTACHMENTS

This request for a Release into the Environment Permit is to allow the field testing of marker genes in genetically modified wheat at the locations specified in item 10. All of the information required to support this application is found in this volume.

The vector constructs that may be a part of this field experiment are:

PV-TXCT01, PV-TXCT02, PV-TXCT03, PV-TXCT04, and PV-TXCT05

Item 6. The following is the information required to identify the donor, recipient, and regulated organisms and vector agent:

a) For Cotransformation Event PV-TXCT01:

Plasmid vector PV-TXGT01:

		Scientific Name	Common Name
CBI CBI CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM01:

		Scientific Name	Common Name
CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

b) For Cotransformation Event PV-TXCT02:

Plasmid vector PV-TXGT02:

		Scientific Name	Common Name
CBI CBI CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM02:

		Scientific Name	Common Name
CBI	a. Donor Organism	(b) (4) *Escherichia coli*	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

c) For Cotransformation Event PV-TXCT03:

Plasmid vector PV-TXGT03:

		Scientific Name	Common Name
CBI CBI CBI CBI	a.Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM03:

		Scientific Name	Common Name
CBI CBI	a. Donor Organism	[redacted] (b) (4) *Escherichia coli*	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

d) For Cotransformation Event PV-TXCT04:

Plasmid vector PV-TXSM04:

		Scientific Name	Common Name
CBI	a. Donor Organism	[redacted] (b) (4) TN5	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM01:

		Scientific Name	Common Name
CBI	a. Donor Organism	[redacted] (b) (4) *Escherichia coli*	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

e) For Cotransformation Event PV-TXCT04:

Plasmid vector PV-TXSM04:

		Scientific Name	Common Name
CBI	a. Donor Organism	[redacted] (b) (4) TN5	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM05

	Scientific Name	Common Name
a. Donor Organism	*Zea mays*	corn
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

CONSTRUCT DESCRIPTION FOR PV-TXCT01

In this instance, PV-TXGT01 AND TXSM01 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT01

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**(b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI (b) (4)

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.

CBI (b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT01 (Contin.)

CBI **CMoVa/**(b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI (b) (4)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.

CBI (b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**(b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI (b) (4)

GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT01 (Contin.)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

Replacement pg
2/23/94 DLO

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT02

In this instance, PV-TXGT02 AND TXSM02 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT02

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMP1/[ ] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

CBI DELETED

]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.
[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMP1/[ ] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

CBI DELETED

]

OR120018_BR_011500

Replacement pg
2/23/94 MC

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT02

In this instance, PV-TXGT02 AND TXSM02 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT02

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMP1/**(b) (4) The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI (b) (4)

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.

CBI (b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI **CMP1/**(b) (4) The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI (b) (4)

OR120018_BR_011501

Replacement pg
2/23/94 NRO

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT02 (Contin.)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.

CBI



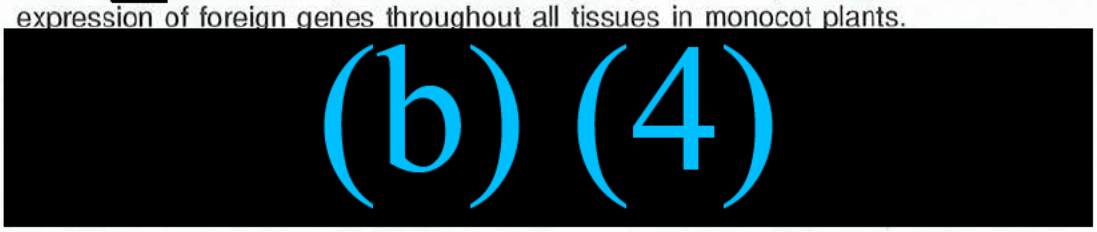
NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM02

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMP1/**(b) (4) The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI



GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011502

Replacement pg
2/23/94 NRO

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT03

In this instance, PV-TXGT03 AND TXSM03 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT03

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMP2/**[redacted] The CMP2 (Constitutive monocot promoter 2) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [redacted]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.

CBI [redacted]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI **CMP2/**[redacted] The CMP2 (Constitutive monocot promoter 2) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [redacted]

OR120018_BR_011503

Replacement pg
2/23/94 NAO

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT03 (Contin.)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.

CBI



NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM03

This construct is a free delivery: pUC-Kan vector containing 1 genes (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMP2/**(b) (4) The CMP2 (Constitutive monocot promoter 2) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI



GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011504

CONSTRUCT DESCRIPTION FOR PV-TXCT04

In this instance, PV-TXSM04 AND TXSM01 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 gene (the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**(b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [redacted]

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXCT04 (Contin.)

CONSTRUCT DESCRIPTION FOR PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/[I2]** A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [redacted]

GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT05

In this instance, PV-TXSM04 AND TXSM05 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 gene (the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**(b) (4)A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI (b) (4)

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT05 (Contin.)

CONSTRUCT DESCRIPTION FOR PV-TXSM05

This construct is a free delivery: pUC-Amp vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

35S The 0.35 Kb cauliflower mosaic virus (CaMV) 35S promoter region (Odell et al. 1985, Nature 313:810-812; Gardner, et al. 1981, NAR. 9 (12):2871-2898; and Sanders, et al. 1987, NAR 15:1543-1558).

Bperu Expression of this gene will activate the pathway for anthocyanin biosynthesis in plants of the appropriate genetic background. The B gene is a 2.0 Kb cDNA sequence from Zea maize (Chandler V.L.et al. 1989. Plant Cell 1: 1175-1183).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

35S The 0.35 Kb cauliflower mosaic virus (CaMV) 35S promoter region (Odell et al. 1985, Nature 313:810-812; Gardner, et al. 1981, NAR. 9 (12):2871-2898; and Sanders, et al. 1987, NAR 15:1543-1558).

C1 Expression of this gene will activate the pathway for anthocyanin biosynthesis in plants of the appropriate genetic background. The C1 gene is a 1.1 Kb cDNA sequence from Zea maize (Pas-Arez, J. et al. 1987. EMBO 6:3553-3555).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011508

Item 9: The donor, recipient and vector organisms were collected in the United States. The vector construct and transgenic wheat were developed by Monsanto at the Chesterfield Village Laboratories. The planting material will be wheat seeds produced by and shipped from:

(b) (6), (b) (7)(C)
The Agricultural Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
Tel.: (b) (6), (b) (7)(C)
Fax: 314-537-6950

Item 10. The locations of the field experiment is as follows:

(b) (4) **Montana**
Yellowstone County

Principle Investigator: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) MT (b) (4), (b) (6), (b) (7)(C)
tel: (b) (4), (b) (6), (b) (7)(C)

Item 13a. The transgenic wheat which is the subject of this permit request, was developed by scientists at Monsanto. For additional information contact the applicant of this permit.

Item 13b. The transgenic material that is the recipient of the added genes is the CIMMYT(Centro Internaclonal de Mejoramiento de Maiz y Trigo, Facimile 52-595-41069) line Bobwhite. The line Bobwhite was designated to a group of advanced lines derived from the cross Aurora/Kalyan/Bluebird/3/Woodpecker CM33203. This cross was made at CIMMYT in 1973.

Bobwhite is in general semidwarf, carries resistance to septoria tritici, leaf rust, and the gene YR9 for stripe rust. The Bobwhite lines carry the 1B/1R translocation i.e. 1BS is translocated by 1RS of rye. The 1B/1R was derived from the variety Aurora from the USSR. Despite the fact that it carries 1B/1R translocation associated with poor quality(stickiness), industrial quality of Bobwhite is good, and acceptable in most countries.

The Bobwhite line has been genetically -modified by particle bombardment for co-transformation of one of the scorable or selectable markers described . At present no molecular or segregation data is available from the lines that will be evaluated in the field trial. However the original transformed plants have been qualitatively evaluated for gene expression of the selectable marker/s with positive results.

Item 13c. The description of the plasmid vector as inserted into these wheat plants is found on the following pages.

CONTAINS C B I

VECTOR DESCRIPTION FOR FREE DELIVERY

Free delivery vectors are engineered to contain multiple chimeric plant expression genes in either the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11) or pMON 10081, a derivative of the high copy *E. coli* plasmid pUC119. These vectors contain either the B-lactamase gene conferring bacterial ampicillin resistance (pUC119) or the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance (pMON 10081). The antibiotic markers are driven by bacterial promoters which do not contain the regulatory elements necessary to express in plants. They are also used to propagate the plasmid in *E. coli* in order to produce sufficient DNA quantities for transformation experiments (further described in Delivery System Description).

FREE DELIVERY PARTICLE GUN (MONSANTO)

Introduction of DNA into plant tissue with the "biolistic" particle bombardment method has been described in detail by Klein et al. (1987, Nature 327: 70-73; 1988a, Bio/Technology 6: 559-563; and 1988b, Proc Natl Acad Sci USA 85: 4305-4309). The transgenic material in this application was produced using the commercially available PDS1000 particle delivery system (originally leased from DuPont, now available through Bio-Rad Laboratories). Detailed instructions are available from the manufacturers. Briefly, DNA is precipitated onto microscopic (~1 μ diameter) tungsten or gold particles using calcium chloride and spermidine. A drop (2.5μl) of the coated particles is then placed onto a plastic macrocarrier, which is accelerated at a high velocity through a barrel by the explosive force of a gunpowder discharge. The macrocarrier hits a plastic "stopping plate" which stops the flight of the macrocarrier but allows continued flight of the DNA-coated particles. The particles penetrate the target plant cells, where the DNA is deposited and incorporated into the plant cell genome. The cells are incubated on a tissue culture medium which supports the growth of embryogenic callus. The introduced DNA contains a gene(s) encoding for resistance to either antibiotics (e.g., the NPTII gene for resistance to kanamycin and G418) or genes conferring resistance to glyphosate. The plant cells are grown in the presence of an appropriate antibiotic or glyphosate, and only the transformed cells continue grow. Plants are regenerated from the resistant embryogenic callus tissue, and are assayed for the presence of the introduced gene(s). The free delivery vectors are engineered to contain multiple chimeric plant expression genes in the high copy E. coli plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). The pUC119 plasmid contains the ß-lactamase gene conferring bacterial ampicillin resistance. Several chimeric plant expression genes can be introduced into pUC119. These include the marker genes required for selection of the transformed plant tissue, and one or more genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

OR120018_BR_011510

CONTAINS C B I

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Amp

The free delivery vectors are engineered to contain multiple chimeric plant expression genes in the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). The pUC119 plasmid contains the ß-lactamase gene conferring bacterial ampicillin resistance. Several chimeric plant expression genes can be introduced into pUC119. These include the marker genes required for selection of the transformed plant tissue, and one or more genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Kan

The free delivery vectors contain multiple chimeric plant expression genes engineered into pMON10081. The pMON10081 plasmid is a derivative of the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). It was constructed by fusing the 1.3 Kb FspI-DraI origin of replication fragment from pUC119, to the 1.3 Kb SmaI-HindIII (Klenow filled) fragment from pKC7 (Rao and Rogers 1979, Gene 7: 79). The pKC7 fragment contains the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance. The ß-lactamase gene conferring bacterial ampicillin resistance was completely deleted. Several chimeric plant expression genes can be introduced into pMON10081. These include the marker genes required for selection of the transformed plant tissue, and one or more chimeric genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

OR120018_BR_011511

Item 13d. The plasmid vectors were constructed at the research laboratories of Monsanto Co. in St. Louis, Missouri. The initial wheat plants transformed with these vectors were also developed at the research laboratories of Monsanto Co. in St. Louis, Missouri, USA.

Item 13e. The information regarding the description of the propose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design is found in the following protocol:

PROPOSED EXPERIMENTAL PROGRAM

MARKER GENES IN GENETICALLY MODIFIED WHEAT

Purpose of the test:

To test the efficacy of various marker genes in wheat.

Investigators:

* Principal Monsanto investigator at St. Louis, MO:

(b) (6), (b) (7)(C)
The Agriculture Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
phone: (b) (6), (b) (7)(C)
FAX: (314) 537-6950

* Principal investigator at field site:

(b) (6), (b) (7)(C), (b) (4)
MT
phone: (b) (6), (b) (7)(C), (b) (4)

Field Test Design:

* The test will use an experimental design that best addresses the test objectives while dealing with limited seed quantities.

* Treatments will be chosen from the following:

    * Chemical herbicide: Use of commercially available herbicides or proprietary chemistry to evaluate the effects of application on weed control and crop tolerance.

CONTAINS C B I

* Timing of application: Chosen from growth stages between emergence through first flowering including sequential applications at two or more growth stages.

* Type of application: Over-the-top or post-directed.

Genotypes:

* Homozygous and segregating progeny of lines transformed with one of the following vectors:

  PV-TXCT01
  PV-TXCT02
  PV-TXCT03
  PV-TXCT04
  PV-TXCT05

* Non-transgenic Bobwhite.

Plot design:

* Each plot will consist of one to four rows, 4-12 inches apart and up to 20 feet long.

* A standard experimental design will be utilized such as a randomized complete block design or a split plot design.

* The number of replications will be determined by seed availability. The anticipated number of replications is from one to four.

Space requirements:

* The transgenic material will cover less than 1.0 acre with no more than 500,000 plants.

* The experiment including the border will cover less than 1.2 acres.

* The total area needed for the entire test (including borders and alleyways) will be no greater than 1.5 acres.

Isolation:

This trial will be isolated from other wheat according to the standards set forth by Association of Official Seed Certifying Agencies in the "Certification Handbook." In using these guidelines for reference, the wheat in this trial will be separated from other wheat by a 20 foot strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat.

Tentative schedule:

* Planting: March 15 to May 15 depending on weather and seed availability.

* Harvest: July 1 to August 31 depending on weather and date of planting.

CONTAINS C B I

Agronomic practices:

* Ground preparation and fertility: Ground prepartion will follow normal practices for wheat. Fertilizer may be applied based on a soil test to bring the nutrient level up to that recommended for wheat. Additional fertilizer may be applied throughout the season as needed.

* Weed control: Weed control will follow acceptable practices for wheat by using labelled herbicides, experimental herbicides, and/or hand weeding.

* Disease control: Diseases will be controlled by the use of labelled fungicides for seed treatment and/or topical applications.

* Insect control: Insect pests will be monitored for their appearance in the field. Insecticides labelled to control insect pests that are present will be applied as needed, including seed treatments or topical applications.

Harvest procedures:

* The wheat will be harvested by hand or with a field plot harvester. If a machine is used, it will be thoroughly cleaned prior to exiting the plot area.

Plant and seed disposal:

* Some seed will be sent to Monsanto laboratories in Chesterfield, MO for further analysis. After data collection and harvest, all remaining seed not sent to Monsanto will be either clearly marked and stored in a secure facility at the site or destroyed on the site by distribution in the field. The seed and remaining plant stubble will be mechanically incorporated into the soil. After the experiment is concluded, the plot area will be monitored for 8 months for germinating seed which will be destroyed with tillage or herbicide treatment.

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CONTAINS C B I

SITE SPECIFIC INFORMATION

(b) (4) **Montana**
Yellowstone County

Principle Investigator: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) MT (b) (6), (b) (7)(C), (b) (4)
tel: (b) (6), (b) (7)(C), (b) (4)
fax: 406-652-7846

Site Description:

(b) (4)

Item 13f. All research and procedures used in the production of the donor organism, recipient organism, vector or vector agent and the transgenic wheat were done utilizing level BL2 containment according to the NIH Guidelines for Recombinant DNA Research. All transgenic plants and their clonally propagated "progeny" have been repeatedly tested, and do not contain *Agrobacterium* cells.

Items 13g and h: None of the wheat seed or plant material produced in this experiment will enter commerce or will be consumed by domestic animals.

Seed will be taken to the field sites in containers fastened to preclude spillage. Movement will be in an enclosed vehicle. Up to three movements to each field site are anticipated. There will be up to 20 pounds of seed totaled over the three movements to each site. Movements should occur from March 1 - July 1, 1993.

Isolation:

This trial will be isolated from other wheat according to the standards set forth by Association of Official Seed Certifying Agencies in the "Certification Handbook." In using these guidelines for reference, the wheat in this trial will be separated from other wheat by a 20 foot strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat.

Harvest:

Plots will be harvested, either by hand or by machine. If a machine is used, it will be thoroughly cleaned prior to exiting the plot area.

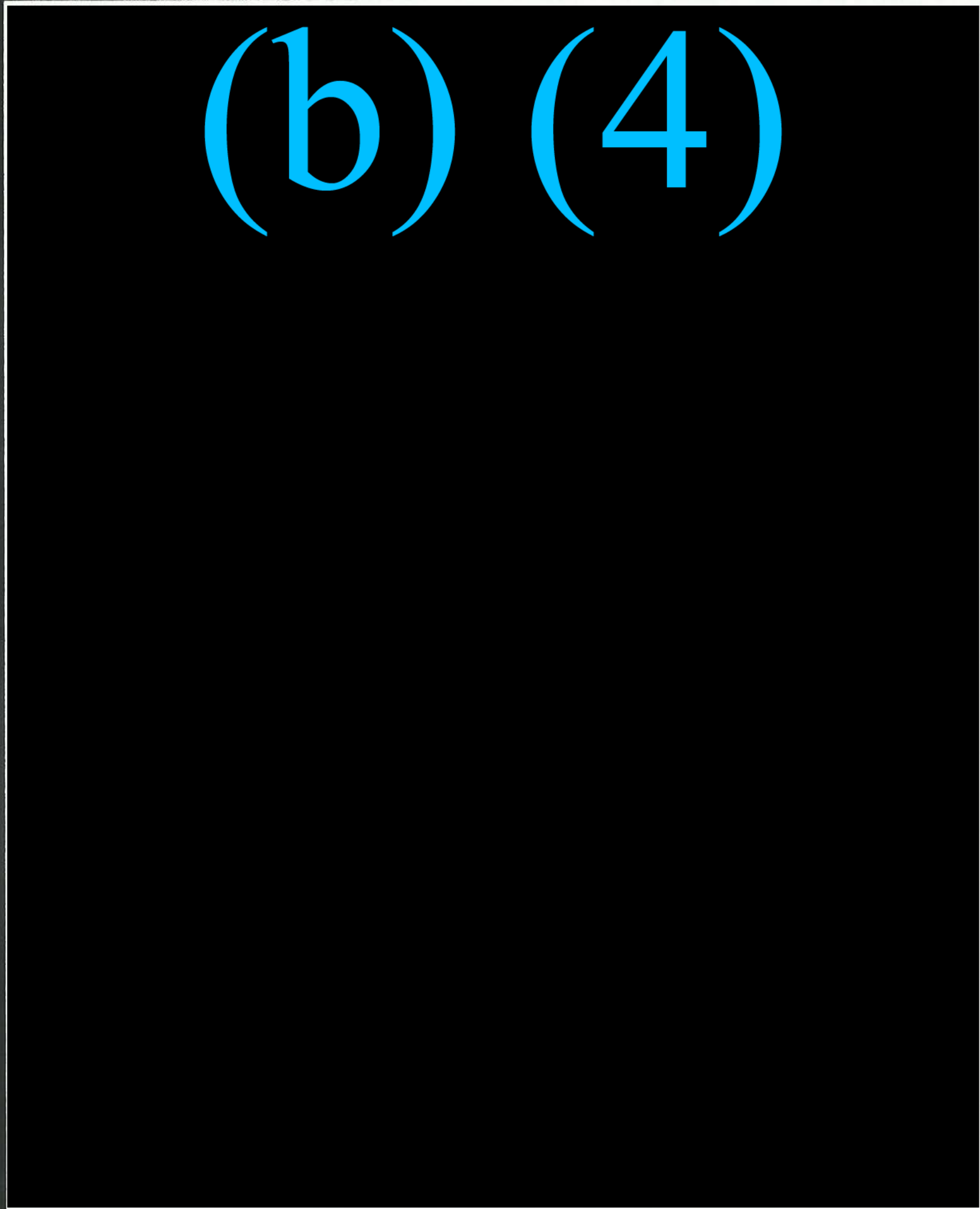
OR120018_BR_011515

CONTAINS C B I

Item 13i. Following harvest, some seed will be sent to Monsanto laboratories in Chesterfield, Missouri for further analysis. After data collection and harvest, all remaining seed not sent to Monsanto will be either clearly marked and stored in a secure facility on site or destroyed on the site by distribution in the field. The seed and remaining plant stubble will be mechanically incorporated into the soil.

After the experiment is concluded, the plot area will be monitored for one year for plants. Any such volunteers will be killed through cultivation and/or herbicide treatment.

OR120018_BR_011516


(b) (4)

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (IOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (IOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.[1]

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of marker genes in plants and their use in insect and virus resistant and herbicide tolerant crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

[1] In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011519

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Calgene, Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

OR120018_BR_011520

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for wheat has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

OR120018_BR_011521

ATTACHMENT
CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION
MARKER GENES IN WHEAT

Page	Category of Information	Justification
1	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011522

2	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011523

6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011524

9	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011525

12	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
13	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
13	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
14	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
14	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

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...application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq.) and the Plant Quarantine Act (7 U.S.C. 151 et seq.). The information will be used to determine eligibility to receive all types of permits. No permit shall be issued until this application has been approved.

See reverse side for additional information

FORM APPROVED
OMB NO. 0579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

(Genetically Engineered Organisms or Products)

93-182R

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

1. NAME AND ADDRESS OF APPLICANT

(b) (6), (b) (7)(C)

Monsanto Agricultural Company BB3A
700 Chesterfield Parkway North, St. Louis, MO 63198

Area Code (314) 537-7488

2. PERMIT REQUESTED ("X" one)

- [ ] Limited - Interstate Movement
- [ ] Limited - Importation
- [x] Release into the Environment
- [ ] Courtesy Permit

3. THIS REQUEST IS ("X" one)

- [x] New
- [ ] Renewal
- [ ] Supplemental

4. TELEPHONE NUMBER

(314) 537-7488

5. MEANS OF MOVEMENT

- [x] Mail
- [ ] Baggage or Handcarried
- [x] Common Carrier
- By whom _____

6. GIVE THE FOLLOWING *(if applicable) (if more space is needed, attach additional sheet)*

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism	See Attached			
b. Recipient Organism				
c. Vector or Vector Agent				
d. Regulated Organism or Product				
e. If product, list names of constituents				

7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS

See attached

8. DATE *(or inclusive dates of period)* **OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE**

Mar. 1, 1994 - Nov. 1, 1994

9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

See attached

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

See Attached

11. ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* **ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT**

None

12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

N/A

13. SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON	15. PRINTED NAME AND TITLE	16. DATE
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	1/13/94

FOR APHIS USE ONLY

State Notification Sent	State Review Received	Permit Issued
February 24, 1994	March 11, 1994	[XX] Yes [ ] No

Date of Determination	Permit No.	No. of Permit Labels Issued	Supplemental Conditions Enclosed
May 25, 1994	94-024-01r	n/a	[XX] Yes [ ] No

Signature of BBEP Official	Date	Expiration Date
Arnold Foudin, Deputy Director, BP	MAY 26 1994	MAY 26 1995

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APHIS FORM 2000 *Replaces PPQ Form 1001 which may be used*

(continued on reverse)

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	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article	X	
b	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e g , morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics)	X	
c	A detailed description of the molecular biology of the system (e g , donor-recipient-vector) which is or will be used to produce the regulated article	X	
d	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced	X	
e	A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design	X	
f	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the donor organism, recipient organism, vector or vector agent, constituent of each regulated article which is a product and regulated article	X	
g	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e g greenhouses, laboratory, or growth chamber location, field trial location, pilot project location, production, propagation, and manufacture location, proposed sale and distribution location)	X	
	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations	X	
i	A detailed description of the proposed method of final disposition of the regulated article	X	

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

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94-024-01
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INFORMATION SUBMITTED TO
THE UNITED STATES DEPARTMENT OF AGRICULTURE
IN SUPPORT OF AN APPLICATION TO FIELD TEST

TESTING OF MARKER GENES IN GENETICALLY ENGINEERED WHEAT PLANTS

93-182PR

January 14, 1994

Volume 1 of 1

Report Compiled by:
(b) (6), (b) (7)(C)

Confidential Business Information Deleted

MONSANTO AGRICULTURAL COMPANY
700 Chesterfield Parkway North • St. Louis • Missouri • 63198

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State of Montana	-	1 Copy
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OR120018_BR_011530

TABLE OF CONTENTS

page

VOLUME 1

APHIS FORM 2000

APHIS FORM 2000 ATTACHMENTS 1

OR120018_BR_011531

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APHIS FORM 2000 ATTACHMENTS

This request for a Release into the Environment Permit is to allow the field testing of marker genes in genetically modified wheat at the locations specified in item 10. All of the information required to support this application is found in this volume.

The vector constructs that may be a part of this field experiment are:

PV-TXCT01, PV-TXCT02, PV-TXCT03, PV-TXCT04, and PV-TXCT01

Item 6. The following is the information required to identify the donor, recipient, and regulated organisms and vector agent:

a) For Cotransformation Event PV-TXCT01:

Plasmid vector PV-TXGT01:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] [CBI DELETED] [CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM01:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] *Escherichia coli*	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

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b) For Cotransformation Event PV-TXCT02:

Plasmid vector PV-TXGT02:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] [CBI DELETED] [CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM02:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] *Escherichia coli*	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

c) For Cotransformation Event PV-TXCT03:

Plasmid vector PV-TXGT03:

	Scientific Name	Common Name
a.Donor Organism	[CBI DELETED] [CBI DELETED] [CBI DELETED] [CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

CBI DELETED

Plasmid vector PV-TXSM03:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] [CBI DELETED] *Escherichia coli*	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

d) For Cotransformation Event PV-TXCT04:

Plasmid vector PV-TXSM04:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] TN5	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM01:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] *Escherichia coli*	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

CBI DELETED

e) **For Cotransformation Event PV-TXCT04:**

Plasmid vector PV-TXSM04:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] TN5	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM05

	Scientific Name	Common Name
a. Donor Organism	*Zea mays*	corn
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

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CONSTRUCT DESCRIPTION FOR PV-TXCT01

In this instance, PV-TXGT01 AND TXSM01 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT01

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
[

CBI DELETED

]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.
[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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CONSTRUCT DESCRIPTION FOR PV-TXCT01 (Contin.)

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
[

CBI DELETED

]

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.
[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
[

CBI DELETED

]

GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT01 (Contin.)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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Replacement pg 2/23/94 MD

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CONSTRUCT DESCRIPTION FOR PV-TXCT02 (Contin.)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.
[

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]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM02

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMP1/[ ] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

CBI DELETED

]

GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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Replacement pg
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CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT03

In this instance, PV-TXGT03 AND TXSM03 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT03

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMP2/[ ] The CMP2 (Constitutive monocot promoter 2) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

CBI DELETED

]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.
[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMP2/[ ] The CMP2 (Constitutive monocot promoter 2) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

CBI DELETED

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Replacement pg
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CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT03 (Contin.)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.
[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM03

This construct is a free delivery: pUC-Kan vector containing 1 genes (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMP2/[ ] The CMP2 (Constitutive monocot promoter 2) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

CBI DELETED

]

GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011541

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT04

In this instance, PV-TXSM04 AND TXSM01 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 gene (the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

[

CBI DELETED

]

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011542

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CONSTRUCT DESCRIPTION FOR PV-TXCT04 (Contin.)

CONSTRUCT DESCRIPTION FOR PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

[

CBI DELETED

]

GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011543

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT05

In this instance, PV-TXSM04 AND TXSM05 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 gene (the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
[

CBI DELETED

]

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011544

COB I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM05

This construct is a free delivery: pUC-Amp vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

35S The 0.35 Kb cauliflower mosaic virus (CaMV) 35S promoter region (Odell et al. 1985, Nature 313:810-812; Gardner, et al. 1981, NAR. 9 (12):2871-2898; and Sanders, et al. 1987, NAR 15:1543-1558).

Bperu Expression of this gene will activate the pathway for anthocyanin biosynthesis in plants of the appropriate genetic background. The B gene is a 2.0 Kb cDNA sequence from Zea maize (Chandler V.L.et al. 1989. Plant Cell 1: 1175-1183).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

35S The 0.35 Kb cauliflower mosaic virus (CaMV) 35S promoter region (Odell et al. 1985, Nature 313:810-812; Gardner, et al. 1981, NAR. 9 (12):2871-2898; and Sanders, et al. 1987, NAR 15:1543-1558).

C1 Expression of this gene will activate the pathway for anthocyanin biosynthesis in plants of the appropriate genetic background. The C1 gene is a 1.1 Kb cDNA sequence from Zea maize (Pas-Arez, J. et al. 1987. EMBO 6:3553-3555).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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Item 9: The donor, recipient and vector organisms were collected in the United States. The vector construct and transgenic wheat were developed by Monsanto at the Chesterfield Village Laboratories. The planting material will be wheat seeds produced by and shipped from:

(b) (6), (b) (7)(C)
The Agricultural Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
Tel.: (b) (6), (b) (7)(C)
Fax: 314-537-6950

Item 10. The locations of the field experiment is as follows:

(b) (4) **Montana**
Yellowstone County

Principle Investigator: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) MT (b) (6), (b) (7)(C), (b) (4)

tel: (b) (6), (b) (7)(C), (b) (4)

Item 13a. The transgenic wheat which is the subject of this permit request, was developed by scientists at Monsanto. For additional information contact the applicant of this permit.

Item 13b. The transgenic material that is the recipient of the added genes is the CIMMYT(Centro Internaclonal de Mejoramiento de Maiz y Trigo, Facimile 52-595-41069) line Bobwhite. The line Bobwhite was designated to a group of advanced lines derived from the cross Aurora/Kalyan/Bluebird/3/Woodpecker CM33203. This cross was made at CIMMYT in 1973.

Bobwhite is in general semidwarf, carries resistance to septoria tritici, leaf rust, and the gene YR9 for stripe rust. The Bobwhite lines carry the 1B/1R translocation i.e. 1BS is translocated by 1RS of rye. The 1B/1R was derived from the variety Aurora from the USSR. Despite the fact that it carries 1B/1R translocation associated with poor quality(stickiness), industrial quality of Bobwhite is good, and acceptable in most countries.

The Bobwhite line has been genetically -modified by particle bombardment for co-transformation of one of the scorable or selectable markers described . At present no molecular or segregation data is available from the lines that will be evaluated in the field trial. However the original transformed plants have been qualitatively evaluated for gene expression of the selectable marker/s with positive results.

Item 13c. The description of the plasmid vector as inserted into these wheat plants is found on the following pages.

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VECTOR DESCRIPTION FOR FREE DELIVERY

Free delivery vectors are engineered to contain multiple chimeric plant expression genes in either the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11) or pMON 10081, a derivative of the high copy *E. coli* plasmid pUC119. These vectors contain either the B-lactamase gene conferring bacterial ampicillin resistance (pUC119) or the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance (pMON 10081). The antibiotic markers are driven by bacterial promoters which do not contain the regulatory elements necessary to express in plants. They are also used to propagate the plasmid in *E. coli* in order to produce sufficient DNA quantities for transformation experiments (further described in Delivery System Description).

FREE DELIVERY PARTICLE GUN (MONSANTO)

Introduction of DNA into plant tissue with the "biolistic" particle bombardment method has been described in detail by Klein et al. (1987, Nature 327: 70-73; 1988a, Bio/Technology 6: 559-563; and 1988b, Proc Natl Acad Sci USA 85: 4305-4309). The transgenic material in this application was produced using the commercially available PDS1000 particle delivery system (originally leased from DuPont, now available through Bio-Rad Laboratories). Detailed instructions are available from the manufacturers. Briefly, DNA is precipitated onto microscopic (~1 μ diameter) tungsten or gold particles using calcium chloride and spermidine. A drop (2.5μl) of the coated particles is then placed onto a plastic macrocarrier, which is accelerated at a high velocity through a barrel by the explosive force of a gunpowder discharge. The macrocarrier hits a plastic "stopping plate" which stops the flight of the macrocarrier but allows continued flight of the DNA-coated particles. The particles penetrate the target plant cells, where the DNA is deposited and incorporated into the plant cell genome. The cells are incubated on a tissue culture medium which supports the growth of embryogenic callus. The introduced DNA contains a gene(s) encoding for resistance to either antibiotics (e.g., the NPTII gene for resistance to kanamycin and G418) or genes conferring resistance to glyphosate. The plant cells are grown in the presence of an appropriate antibiotic or glyphosate, and only the transformed cells continue grow. Plants are regenerated from the resistant embryogenic callus tissue, and are assayed for the presence of the introduced gene(s). The free delivery vectors are engineered to contain multiple chimeric plant expression genes in the high copy E. coli plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). The pUC119 plasmid contains the ß-lactamase gene conferring bacterial ampicillin resistance. Several chimeric plant expression genes can be introduced into pUC119. These include the marker genes required for selection of the transformed plant tissue, and one or more genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

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VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Amp

The free delivery vectors are engineered to contain multiple chimeric plant expression genes in the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). The pUC119 plasmid contains the ß-lactamase gene conferring bacterial ampicillin resistance. Several chimeric plant expression genes can be introduced into pUC119. These include the marker genes required for selection of the transformed plant tissue, and one or more genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Kan

The free delivery vectors contain multiple chimeric plant expression genes engineered into pMON10081. The pMON10081 plasmid is a derivative of the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). It was constructed by fusing the 1.3 Kb FspI-DraI origin of replication fragment from pUC119, to the 1.3 Kb SmaI-HindIII (Klenow filled) fragment from pKC7 (Rao and Rogers 1979, Gene 7: 79). The pKC7 fragment contains the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance. The ß-lactamase gene conferring bacterial ampicillin resistance was completely deleted. Several chimeric plant expression genes can be introduced into pMON10081. These include the marker genes required for selection of the transformed plant tissue, and one or more chimeric genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

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Item 13d. The plasmid vectors were constructed at the research laboratories of Monsanto Co. in St. Louis, Missouri. The initial wheat plants transformed with these vectors were also developed at the research laboratories of Monsanto Co. in St. Louis, Missouri, USA.

Item 13e. The information regarding the description of the propose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design is found in the following protocol:

PROPOSED EXPERIMENTAL PROGRAM

MARKER GENES IN GENETICALLY MODIFIED WHEAT

Purpose of the test:

To test the efficacy of various marker genes in wheat.

Investigators:

* Principal Monsanto investigator at St. Louis, MO:

(b) (6), (b) (7)(C)
The Agriculture Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
phone: (b) (6), (b) (7)(C)
FAX: (314) 537-6950

* Principal investigator at field site:

(b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) MT (b) (6), (b) (7)(C), (b)
phone (b) (6), (b) (7)(C), (b) (4)

Field Test Design:

* The test will use an experimental design that best addresses the test objectives while dealing with limited seed quantities.

* Treatments will be chosen from the following:

    * Chemical herbicide: Use of commercially available herbicides or proprietary chemistry to evaluate the effects of application on weed control and crop tolerance.

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* Timing of application: Chosen from growth stages between emergence through first flowering including sequential applications at two or more growth stages.

* Type of application: Over-the-top or post-directed.

Genotypes:

* Homozygous and segregating progeny of lines transformed with one of the following vectors:

  PV-TXCT01
  PV-TXCT02
  PV-TXCT03
  PV-TXCT04
  PV-TXCT05

* Non-transgenic Bobwhite.

Plot design:

* Each plot will consist of one to four rows, 4-12 inches apart and up to 20 feet long.

* A standard experimental design will be utilized such as a randomized complete block design or a split plot design.

* The number of replications will be determined by seed availability. The anticipated number of replications is from one to four.

Space requirements:

* The transgenic material will cover less than 1.0 acre with no more than 500,000 plants.

* The experiment including the border will cover less than 1.2 acres.

* The total area needed for the entire test (including borders and alleyways) will be no greater than 1.5 acres.

Isolation:

This trial will be isolated from other wheat according to the standards set forth by Association of Official Seed Certifying Agencies in the "Certification Handbook." In using these guidelines for reference, the wheat in this trial will be separated from other wheat by a 20 foot strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat.

Tentative schedule:

* Planting: March 15 to May 15 depending on weather and seed availability.

* Harvest: July 1 to August 31 depending on weather and date of planting.

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Agronomic practices:

* Ground preparation and fertility: Ground prepartion will follow normal practices for wheat. Fertilizer may be applied based on a soil test to bring the nutrient level up to that recommended for wheat. Additional fertilizer may be applied throughout the season as needed.

* Weed control: Weed control will follow acceptable practices for wheat by using labelled herbicides, experimental herbicides, and/or hand weeding.

* Disease control: Diseases will be controlled by the use of labelled fungicides for seed treatment and/or topical applications.

* Insect control: Insect pests will be monitored for their appearance in the field. Insecticides labelled to control insect pests that are present will be applied as needed, including seed treatments or topical applications.

Harvest procedures:

* The wheat will be harvested by hand or with a field plot harvester. If a machine is used, it will be thoroughly cleaned prior to exiting the plot area.

Plant and seed disposal:

* Some seed will be sent to Monsanto laboratories in Chesterfield, MO for further analysis. After data collection and harvest, all remaining seed not sent to Monsanto will be either clearly marked and stored in a secure facility at the site or destroyed on the site by distribution in the field. The seed and remaining plant stubble will be mechanically incorporated into the soil. After the experiment is concluded, the plot area will be monitored for 8 months for germinating seed which will be destroyed with tillage or herbicide treatment.

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SITE SPECIFIC INFORMATION

(b) (4) **Montana**
Yellowstone County

Principle Investigator: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) MT (b) (6), (b) (7)(C), (b) (4)
tel: (b) (6), (b) (7)(C), (b) (4)
fax: 406-652-7846

Site Description:

(b) (4)

Item 13f. All research and procedures used in the production of the donor organism, recipient organism, vector or vector agent and the transgenic wheat were done utilizing level BL2 containment according to the NIH Guidelines for Recombinant DNA Research. All transgenic plants and their clonally propagated "progeny" have been repeatedly tested, and do not contain *Agrobacterium* cells.

Items 13g and h: None of the wheat seed or plant material produced in this experiment will enter commerce or will be consumed by domestic animals.

Seed will be taken to the field sites in containers fastened to preclude spillage. Movement will be in an enclosed vehicle. Up to three movements to each field site are anticipated. There will be up to 20 pounds of seed totaled over the three movements to each site. Movements should occur from March 1 - July 1, 1993.

Isolation:

This trial will be isolated from other wheat according to the standards set forth by Association of Official Seed Certifying Agencies in the "Certification Handbook." In using these guidelines for reference, the wheat in this trial will be separated from other wheat by a 20 foot strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat.

Harvest:

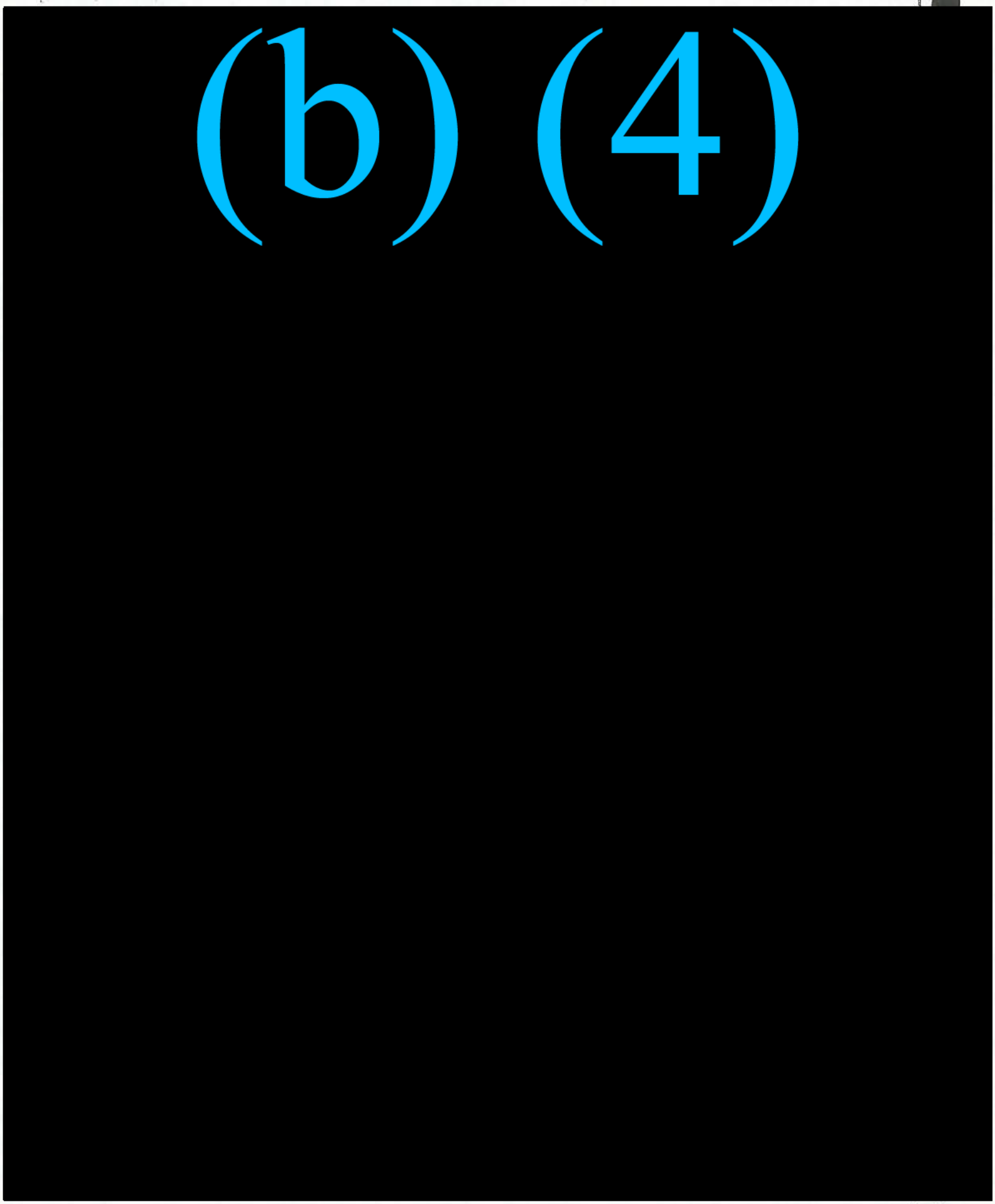
Plots will be harvested, either by hand or by machine. If a machine is used, it will be thoroughly cleaned prior to exiting the plot area.

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Item 13i. Following harvest, some seed will be sent to Monsanto laboratories in Chesterfield, Missouri for further analysis. After data collection and harvest, all remaining seed not sent to Monsanto will be either clearly marked and stored in a secure facility on site or destroyed on the site by distribution in the field. The seed and remaining plant stubble will be mechanically incorporated into the soil.

After the experiment is concluded, the plot area will be monitored for one year for plants. Any such volunteers will be killed through cultivation and/or herbicide treatment.

OR12001B_BR_011553


(b) (4)

APHIS APPLICATION NO. 94-024-01
DATE: FEB 2 4 1994

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

__X__ State concurs with APHIS' initial review.

_____ State concurs with APHIS' initial review and offers the following comments (use additional sheets if necessary):

_____ State does not concur with APHIS' initial review and offers the following reasons for nonconcurrence (use additional sheets if necessary):

Name of State Official: BARBRA MULLIN

Title: Weed Specialist

Agency or Department: MT. Dept of Agriculture
Ag Sciences Division

Address: P.O. Box 200201

City, State, Zip Code: Helena, MT 59620

Signature: (b) (6), (b) (7)(C)

Date: 3 March '94

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

Subhash Gupta
USDA, APHIS, BBEP
Biotechnology Permits, FB Room 843
6505 Belcrest Road
Hyattsville, MD 20782

RECEIVED 3-11-94 RP

OR120018_BR_011555

Monsanto

94-024-01
AMENDMENT

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

February 18, 1994

Att: Dr. Subhash Gupta
Biotechnology Permits
Biotechnology, Biologics, and Environmental Protection
6505 Belcrest Rd, Suite 7
Hyattsville, MD 20782
FAX: 301-436-8910

Dear Dr. Gupta:

This letter and attachments are being sent in regard to our permit application 94-024-01 to conduct a field test of genetically engineered wheat plants that express marker genes. Our internal Monsanto number was 93-182R dated January 14, 1994.

As I discussed earlier, upon internal review of the application it was discovered that a portion of the gene description for CTP2-CP4 on pages 8 (PV-TXCT02) and 10 (PV-TXCT03) had been truncated. These gene descriptions should appear in their complete form as shown on page 5 for CTP-CP4 in construct PV-TXCT01. The gene is identical in all three constructs.

Therefore, attached are substitute pages 8 - 11. Confidential Business Information (CBI) and CBI deleted copies are provided. Thank you for your assistance and I can be reached at (b) (6), (b) (7)(C) if I can provide any further clarification.

Sincerely,

(b) (6), (b) (7)(C)

Attachments

RECEIVED
2-23-94
KP

OR120018_BR_011556

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT02

In this instance, PV-TXGT02 AND TXSM02 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT02

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMP1/**(b) (4) The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI (b) (4)

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.

CBI (b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene

(b) (4)

CBI **CMP1/**(b) (4) The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI (b) (4)

CONTAINS CBI

CONSTRUCT DESCRIPTION FOR PV-TXCT02 (Contin.)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.

CBI



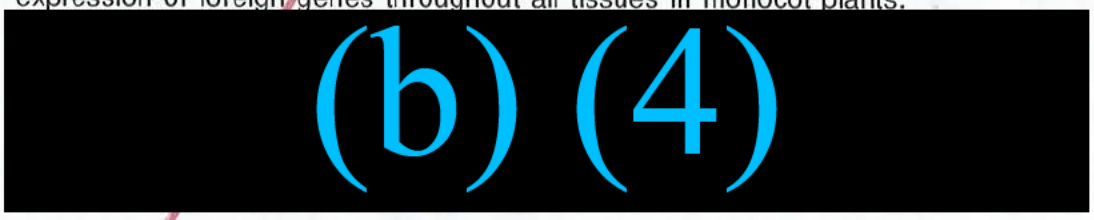
NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM02

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMP1/**(b) (4) The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI



GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT03

In this instance, PV-TXGT03 AND TXSM03 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT03

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMP2/**(b) (4) The CMP2 (Constitutive monocot promoter 2) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI (b) (4)

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.

CBI (b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI **CMP2/**(b) (4) The CMP2 (Constitutive monocot promoter 2) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI (b) (4)

OR120018_BR_011559

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT03 (Contin.)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.

CBI



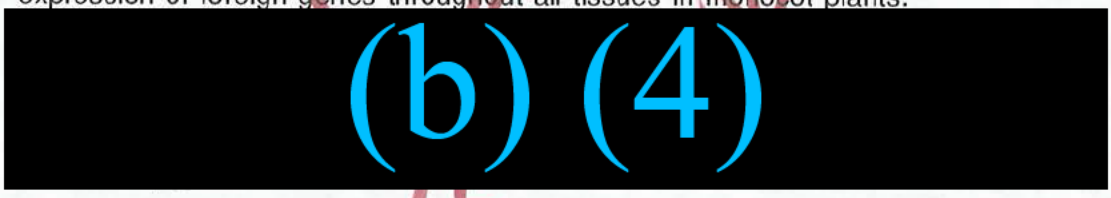
NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM03

This construct is a free delivery: pUC-Kan vector containing 1 genes (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMP2/**(b) (4) The CMP2 (Constitutive monocot promoter 2) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI



GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011560

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT02

In this instance, PV-TXGT02 AND TXSM02 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT02

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMP1/[ ] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

CBI DELETED

]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.
[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMP1/[ ] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

CBI DELETED

]

VOID 6 of 23704 DD

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT02 (Contin.)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.

CBI [

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM02

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMP1/[ ] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

[

CBI DELETED

]

GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

VOID 04 08 1994

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT03

In this instance, PV-TXGT03 AND TXSM03 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT03

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMP2/[ ] The CMP2 (Constitutive monocot promoter 2) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

CBI DELETED

]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.
[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMP2/[ ] The CMP2 (Constitutive monocot promoter 2) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

CBI DELETED

]

VOID 2/23/94

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT03 (Contin.)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.
[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

VOID as of 8/23/94

CONSTRUCT DESCRIPTION FOR PV-TXSM03

This construct is a free delivery: pUC-Kan vector containing 1 genes (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMP2/[ ] The CMP2 (Constitutive monocot promoter 2) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

CBI DELETED

]

GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

FILE COPY

Mr. William A. Kissinger
Montana Department of Agriculture
P.O. Box 200201
Helena, MT 59620

FEB 24 1994

Re: APHIS Preliminary Review of an Application by Monsanto Agricultural Company to Field Test Genetically Engineered Wheat Plants. Accession #94-024-01.

Dear Mr. Kissinger:

This letter contains our preliminary review of an application submitted by Monsanto Agricultural Company for a permit that would allow the field testing of genetically engineered wheat (*Triticum aestivum*) plants. The plants have been modified for expressing marker genes such as kanamycin resistance, herbicide tolerance, and anthocyanin production etc. The field test is proposed to start in May 1993, on agricultural land in Yellowstone County, Montana.

The Monsanto Agricultural Company application was submitted pursuant to the regulations found in 7 CFR Part 340 which regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products that are regulated articles. Under the regulations, an organism is considered a regulated article if it is genetically engineered (as defined in Section 340.1) from a donor organism, recipient organism, or vector or vector agent which is listed in Section 340.2 of the regulations, and the listed organism is a plant pest (as defined in Section 340.1). The regulations require that a person obtain a permit from the Animal and Plant Health Inspection Service (APHIS) prior to introducing a regulated article.

Pursuant to the procedures set forth in Section 340.3 of the regulations, we have prepared our preliminary findings in this letter for your review. This serves to give notice to the State and to provide the opportunity for the State to expressly indicate concurrence or nonconcurrence with our preliminary assessment. Please review the enclosed application documents and return acknowledgement, associated comments, and concurrence or reasons for nonconcurrence (if applicable) to APHIS within 30 days from the date of this letter. Please use the enclosed form, and use additional sheets if needed for your response. It is very important that our office receive comments and opinions from State regulatory officials regarding the issuance of permits for the release of genetically engineered organisms into the environment.

OR120018_BR_011565

On the basis of our preliminary review of this application, we conclude that controlled field testing of the genetically engineered wheat plants described in this application will not present any risk of plant pest introduction or dissemination for the reasons cited below.

1. Environmental Impacts Related to the Recipient. The recipient organisms are wheat plants. Wheat is normally self-pollinated and pollen is viable for only 15 to 20 min, or up to 30 min under the best conditions. Thus, there is a lack of gene movement. To prevent any mechanical mixing, a minimum of 20 feet distance will be maintained between the transgenic and nontransgenic wheat plants.

2. Environmental Impacts Related to the Donor. The wheat plants for this field test have been altered via genetic engineering techniques to contain several different marker genes with different phenotypes, each plant carrying one or two such genes. The exact nature of some of these genes has been claimed as confidential business information (CBI). One of these genes is neomycin phosphotransferase (*nptII*) that encodes resistance to the common antibiotic kanamycin.

Noncoding DNA regulatory sequences (promoters and terminators) were attached to the introduced genes to facilitate expression in plants. These regulatory sequences were derived from a plant pest, specifically cauliflower mosaic virus. None of the DNA regulatory sequences can cause plant disease by themselves or in conjunction with the genes that were introduced into the transgenic plants.

3. Environmental Impacts Related to the Vector and Vector Agent. The wheat plants in this experiment were transformed using the method of particle acceleration, also referred to as the biolistic or particle gun method of transformation. Plant tissues are bombarded with heavy particles, typically tungsten or gold, that are coated with DNA, with the result that particles are able to penetrate the barriers of the cell wall and the cell membrane and deliver the DNA to the interior of the cell. Research experience with transgenic plants produced by the particle acceleration method indicates that the engineered genes are typically integrated into the nuclear genome and segregate in a Mendelian fashion in subsequent generations. No plant pest risk associated with this method of transformation can be identified.

4. Quarantine of Organism and Final Disposition. The test site in Yellowstone County, Montana, is expected to provide adequate physical security. Site monitoring and management practices that create a nonpropagative environment should provide the necessary degree of both biological and physical containment. At maturity, some seeds will be sent to Monsanto laboratories for further analysis. The remaining plant stubble and seeds will be mechanically incorporated into the soil. The containment measures described in the application should be sufficient to minimize any unplanned releases of the transgenic plant material.

OR120018_BR_011566

Staff Contact

If you have any questions about this application or our preliminary findings, please contact Dr. Subhash Gupta, Biotechnologist, at Area Code (301) 436-8365 or facsimile number (301) 436-8669. Please refer to permit application number 94-024-01 in your correspondence regarding this application. APHIS hopes to maintain its excellent working relationship with your State and encourages your participation and comments prior to our final decision.

Sincerely,

/s/ SUBHASH GUPTA PH.D.

Sivramiah Shantharam, Ph.D.
Chief, Microorganisms Branch
Biotechnology Permits
Biotechnology, Biologics, and
Environmental Protection

2 Enclosures

cc:
R. Stoaks, PPQ, WR, Sacramento, CA
S. Ingebritsen, BCTA, Hyattsville, MD
File 94-024-01

APHIS:BBEP:BP:SGUPTA:rp:436-8365:2-23-94:9402401.mt

OR120018_BR_011567

APHIS APPLICATION NO. 94-024-01
DATE: FEB 24 1994

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

_____ State concurs with APHIS' initial review.

_____ State concurs with APHIS' initial review and offers the following comments (use additional sheets if necessary):

_____ State does not concur with APHIS' initial review and offers the following reasons for nonconcurrence (use additional sheets if necessary):

Name of State Official: _____

Title: _____

Agency or Department: _____

_____

Address: P.O. Box 200201

City, State, Zip Code: Helena, MT 59620

Signature: _____

Date: _____

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

Subhash Gupta
USDA, APHIS, BBEP
Biotechnology Permits, FB Room 843
6505 Belcrest Road
Hyattsville, MD 20782

OR120018_BR_011568

(b) (6), (b) (7)(C)
Monsanto Agricultural Products
600 Chesterfield Village Parkway
St. Louis, MO 63198

January 31, 1994

Dear (b) (6), (b) (7)(C)

This is in response to your permit application received January 24, 1994, for release into the environment under 7 C.F.R. §340.

The application for a permit to conduct a field test of genetically engineered wheat plants that express marker genes has been assigned application number 94-024-01. Please refer to this number in correspondence that pertains to this application. You will be notified by letter if further information is needed for this permit application review. The technical reviewer assigned to this application is Dr. Subhash Gupta.

A notice will be published in the Federal Register advising the public of the Animal and Plant Health Inspection Service's (APHIS) receipt of your application. The non-confidential business information copy of your application will be made available to the public through the APHIS Reading Room as specified in the Federal Register, through the Biotechnology Permits Office, and through the Freedom of Information Act Office.

Some States have separate regulations pertaining to release and movement of genetically engineered organisms, therefore it is recommended that you submit your application to the appropriate State(s) at the same time it is submitted to APHIS. This allows the States adequate time to review the application and respond promptly to APHIS' preliminary assessment.

Please call our office at Area Code (301) 436-7612 if you have questions or if we can be of assistance. Thank you for your cooperation.

Sincerely,

/s/

Deborah S. Overton
Biotechnology Permits

cc:
Permit application file 94-024-01

1/31/94

OR120018_BR_011569

OFFICIAL FILE COPY

94-024-01

CONTAINS CBI

MONSANTO

Wheat / Marker genes

STATES: MT

REVIEWER SG

BRANCH CHIEF'S INITS DH

DH
1-25-94

Date 120 days away is 5/24/1994
Date 60 days away is 3/25/1994
Date 30 days away is 2/23/1994

Enter the date you want to count from.
Please enter the Month as an integer (1-12).
and the Day as an integer (1-31).
To exit, Enter -1 for the Year and press return 3 times.

Year: 94 Month: 1 Day: 24

Date 120 days away is 5/24/1994
Date 60 days away is 3/25/1994
Date 30 days away is 2/23/1994

Enter the date you want to count from.
Please enter the Month as an integer (1-12).
and the Day as an integer (1-31).
To exit, Enter -1 for the Year and press return 3 times.

Year:

OR120018_BR_011570

ENVIRONMENTAL ASSESSMENT AND

FINDING OF NO SIGNIFICANT IMPACT

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture has prepared an environmental assessment in response to a permit application (APHIS Number 94-024-01) received from Monsanto Agricultural Company to conduct a field test with genetically engineered (transgenic) wheat (*Triticum aestivum*) plants. These transgenic wheat plants are regulated articles because they were developed with genetic material from known plant pests. The plants have been modified for expressing marker genes such as β-glucuronidase (*gus*), kanamycin resistance, glyphosate herbicide tolerance, and anthocyanin production. The identity of the glyphosate herbicide tolerance gene has been claimed as Confidential Business Information (CBI) by the applicant. The field test is scheduled to begin in June 1994, on agricultural land in Yellowstone County, Montana.

Although parts of the introduced gene constructs were derived from plant pathogens, the test should not pose a risk of the introduction or dissemination of a plant pest. We conclude that the field test will not present a significant impact, either individually or cumulatively, on the quality of the human environment; and have therefore, reached a finding of no significant impact on the environment.

(b) (6), (b) (7)(C)

John H. Payne
Acting Director
Biotechnology, Biologics, and Environmental Protection
Animal and Plant Health Inspection Service
United States Department of Agriculture
Date: MAY 25 1994

key words: Permit number 94-024-01; wheat (*Triticum aestivum*); glyphosate tolerance and kanamycin resistance marker genes

OR120018_BR_011571

I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) has prepared an environmental assessment in response to a permit application (APHIS Number 94-024-01) received from Monsanto Agricultural Company to field test genetically engineered wheat plants. These transgenic wheat plants are regulated articles because they were developed with genetic material from known plant pests. The plants have been modified for expressing marker genes such as β-glucuronidase (*gus*), kanamycin resistance, herbicide tolerance, and anthocyanin production. The identity of the herbicide tolerance gene has been claimed as CBI by the applicant. The field test is scheduled to begin in June 1994, on agricultural land in Yellowstone County, Montana.

The wheat plants in this experiment were transformed using the method of particle acceleration also referred to as the biolistic or particle gun method of transformation. The selectable genetic marker genes aid in the selection of transformed plant tissues in the laboratory. Several of the noncoding DNA regulatory sequences i.e. sequences attached to the coding regions that control expression of the introduced coding sequences, were derived from bacterial and viral plant pathogens. The regulatory sequences cannot cause plant disease by themselves or in conjunction with the coding regions which they regulate in the constructs included in this field test. Once inserted into the chromosome of the recipient, the introduced genes are maintained and transmitted to other plants via pollen, in the same manner as any other genes.

The proposed field test is a controlled release of the regulated article into the environment. The transgenic wheat plants will be planted in plots that are separate from wheat plants not part of the experimental release. It is unlikely that any trait from the transgenic wheat will be transmitted to any other wheat or sexually compatible relative. Hence there will be no significant impact of the transgenic wheat plants in this field trial. This conclusion is based upon both the nature of the genetic modifications in these plants and the fact that genetic material from descendants of such crosses is unlikely to enter into wheat breeding stock or otherwise become established in the environment.

The APHIS review and analysis of the data indicate that the proposed field test should not present a risk of introduction and dissemination of a plant pest and should not have a significant impact, either individually or cumulatively, on the quality of the human environment.

OR120018_BR_011572

II. INTRODUCTION

A permit application was submitted to USDA-APHIS pursuant to regulations codified in 7 CFR Part 340 which are entitled "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests". The regulations govern the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. Under § 340.0 of the regulations, a person is required to obtain a permit prior to introducing a regulated article. Prior to issuing a permit, APHIS prepares an analysis of the potential impacts associated with the proposed introduction, and publishes an environmental assessment which documents the analysis in accordance with regulations and guidelines implementing the National Environmental Policy Act (NEPA) of 1969 (42 USC 4321 *et seq.*); Regulations of the council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500-1508) ; USDA Regulations Implementing NEPA (7 CFR part 1b); APHIS Guidelines Implementing NEPA (44 FR 50381-50384; and 44 FR 51272-51274).

A genetically engineered organism is considered a regulated article if the donor organism, recipient organism, vector or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation and is also a plant pest, or if there is reason to believe that it is a plant pest. The transgenic wheat plants described in this application are considered regulated articles because some of the introduced noncoding DNA regulatory sequences are derived from plant pests/pathogens.

This is the first season for field testing of genetically engineered wheat plants in the United States. From our communication with Agriculture-Canada, we have learnt that similar field test of genetically modified wheat plants have been proposed in Canada.

III. ALTERNATIVES

APHIS has considered the following three alternative responses to the applicant's request for a permit to conduct the proposed field test: (1) deny the permit, (2) issue the permit for the test conditions proposed by the applicant, or (3) issue the permit with the stipulation of additional conditions for conduct of the field test. When APHIS issues field test permits, they typically include additional requirements such as filing field data reports. These field reports help APHIS evaluate the specific field test under permit, and they also provide guidance for evaluating future proposed field tests.

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IV. DESCRIPTION OF THE REGULATED ARTICLE

The transgenic wheat plants have been altered via genetic engineering techniques to contain several different marker genes with different phenotypes, each plant carrying one or two such genes. The exact nature of herbicide tolerant gene has been claimed as CBI. Although some of the genes were derived from natural plant pests, the genes themselves do not code for any trait conferring any plant pest or pathogen characteristic. The genetic marker gene, *nptII* aids in the selection of transformed plant tissues in the laboratory (Flavell et al., 1992; Jefferson et al., 1987). It is derived from *Escherichia coli* and encodes the enzyme neomycin phosphotransferase that confers resistance to the antibiotics neomycin and kanamycin. Another gene that is used as a marker gene is β-glucuronidase gene (*gus*) derived from the bacterium *E. coli*. This gene is also widely used in transgenic plants to facilitate the selection of transformed tissues in the laboratory (Jefferson et al., 1987).

All of the genetic constructs also include well-characterized noncoding DNA regulatory sequences derived from the plant pathogens cauliflower mosaic virus (CaMV). Plant pathogen derived noncoding DNA regulatory sequences include: the *35S* gene promoter from CaMV. None of the regulatory sequences introduced into the transgenic wheat lines can cause plant disease by themselves or in conjunction with the genes they regulate.

The transgenic wheat plants were produced using previously described protocols for transformation via particle acceleration that does not involve any live vector agent (Klein et al., 1992). Once inserted into the chromosome of the recipient, the introduced genes are maintained in the same manner as any other genes.

V. DESCRIPTION OF THE FIELD TEST

Field Experiments. The field test is scheduled to begin in June 1994. The test site will be located on agricultural land in Yellowstone County, Montana. The objective of this field trial is to test the efficacy of various marker genes in wheat. Each test plot will consist of one to four rows, 4-12 inches apart and up to 20 feet long. The anticipated number of replications is from one to four. The transgenic material will cover less than 1.0 acre with no more than 500,000 plants. To prevent any mechanical mixing, a minimum of 20 feet distance will be maintained between the transgenic and nontransgenic wheat plants. The 20 foot strip may be either mowed, uncropped, or planted to a crop other than wheat.

Containment of genetic material. Dissemination of genetic material from the genetically engineered wheat plants is unlikely. Wheat is normally self-pollinated and pollen is viable for only 15 to 20 min, or up to 30 min under the best conditions. Thus, there is a lack of gene movement. To prevent any mechanical mixing, a minimum of 20 feet

OR120018_BR_011574

distance will be maintained between the transgenic and nontransgenic wheat plants.

Field Observation, Monitoring, and Final Disposition of Test Plants. The field test plots will be monitored on a regular basis during the course of the growing season to evaluate agronomic characteristics. As much as possible, normal agricultural practices will be used for the plants grown in the test plots. The wheat will be harvested by hand or with a field plot harvester. If a machine is used, it will be thoroughly cleaned to exiting the plot area. Some seed will be sent to Monsanto laboratories in Chesterfield, MO for further analysis. All residual plant material will be mechanically incorporated into the soil. The site will be monitored following the growing season and any emerging volunteer germinating wheat will be destroyed.

VI. POTENTIAL ENVIRONMENTAL IMPACT

The transgenic wheat plants have been modified by the integration of one of several marker genes including herbicide tolerance to glyphosate. These plants also contain a gene that confers resistance to kanamycin. Other than these modification, the transgenic wheat lines should share the characteristics of the parental, nontransformed wheat cultivars. These modifications are not expected to alter significantly the production of any toxic or deleterious constituents as compared to nontransformed wheat plants. Various safeguard issues as discussed below, concerning transgenic wheat were considered at the workshop convened by The Keystone Center, Colorado (Qualset, 1990).

Potential for Persistence of the Modified Plants in the Environment. The proposed field test is a controlled release of the regulated article into the environment. The wheat plants will be grown under standard agricultural conditions in the field and will be planted in a separate plot from those which are not part of the planned introduction. The test site will be physically separated from other plants, and the plants within the test site will be destroyed at the conclusion of the growing season. The field will be cultivated or plowed as needed to destroy any wheat plants remaining in the field. Volunteer wheat seedlings found during monitoring the following year will be destroyed.

Increased weediness. Wheat is not a weed, and the genetic modifications should not significantly influence the ability of the plants to persist in the environment. Wheat does not reproduce vegetatively when grown in the field, so the only way for the regulated article to persist beyond the growing season is by the production of seeds via sexual reproduction. Jointed goatgrass (*Aegilops cylindricum*) is a major weed problem in the cereal producing areas of the western United States (Donald and Ogg, 1991). There is a risk of transfer of an introduced gene from wheat to jointed goatgrass. However, the likeliness of increasing weediness of non-target organisms is not there because the weed control will follow

OR120018_BR_011575

acceptable practices for wheat by using labelled herbicides and or hand weeding. There are also adequate physical, and biological safety features built into the field that will minimize the chances of outcrossing (see V).

Potential for and Impact of Gene Transfer to Other Plants. It is unlikely that the introduced genes will move inadvertently from the transgenic test plants and persist in the genome of progeny. Like most cultivated varieties of wheat, the transformed cultivars of wheat is self-pollinated and pollen is viable for only 15 to 20 min, or up to 30 min under the best conditions. Therefore, it is unlikely that the introduced genes will be transmitted from the field test plants and become established in the environment.

Impact on Existing Agricultural Uses. The wheat plants have been genetically modified by the integration of one of several marker genes including herbicide tolerance to glyphosate. The objective of this field trial is to test the efficacy of various marker genes in transgenic wheat plants. The use of these plants in the proposed field trial should not affect current agricultural practices with wheat.

Impact on Nontarget Organisms. The genes introduced into the transgenic wheat lines are designed to determine the efficacy of marker genes. They should not increase the likelihood that the plants will produce constituents with toxic or deleterious effects on any nontarget floral or faunal species besides the intended target plants. Any such unexpected effects would be minimal by virtue of being confined to the area within the field plot. Since there is no identifiable direct effect of this field test on any wild plant species, there is no apparent risk to any threatened or endangered plant species.

Cumulative Environmental Effects: The transgenic wheat will not be allowed to persist at the test site beyond the effective termination of the test. Also, physical, biological, and temporal safety features built into the test effectively prevent any potential gene escape from these plants into nontarget organisms. Therefore, there is very little chance for cumulative impacts as a result of introducing genetically modified wheat plants into the environment.

Alteration in Susceptibility to Plant Pathogens. There is no indication that the transgenic wheat plants will be substantially altered in their susceptibility to challenge by pathogens or insects. If there were any unanticipated changes in disease susceptibility, the effects would be confined to these plants and the test plot. The plants in the experimental plot will be monitored for a wide range of agronomic traits, including any abnormal insect populations or unexpected plant diseases. Approved pesticides may be applied, if necessary, in accordance with accepted practices of wheat cultivation.

OR120018_BR_011576

Impact on Human Health. The applicant recognizes that any food and feed uses of the transgenic wheat must be in compliance with the guidelines published in the Federal Register by the United States Food and Drug Administration (57 FR 22984, May 29, 1992).

VII. CONCLUSIONS

The APHIS review and analysis of the data indicate that the proposed field test should not present a risk of introduction and dissemination of a plant pest and should not have a significant impact either individually or cumulatively, on the quality of the human environment. APHIS' conclusion is based on the following:

1. Wheat plants were transformed using the method of particle acceleration also referred to as the biolistic or particle gun method of transformation. The only significant means by which the introduced genes can be transmitted to other organisms is by sexual recombination with sexually compatible plants.

2. Although parts of the gene constructs introduced into the transgenic wheat are derived from plant pathogens, the transgenic plants are not diseased nor do they present any identifiable risk of disease to other plants.

3. Dissemination of genetic material from the genetically engineered wheat plants is unlikely. Wheat is normally self-pollinated and pollen is viable for only 15 to 20 min, or up to 30 min under the best conditions.

4. Site monitoring and management practices that create a nonpropagative environment should provide the necessary degree of both biological and physical containment.

APHIS concludes that the proper alternative is to issue the permit with supplemental permit conditions (see Appendix A). These conditions include a requirement for a data report which will aid APHIS in the evaluation of the specific field test under permit and will provide guidance for evaluating future proposed field tests.

OR120018_BR_011577

VIII. LITERATURE CITED

Donald, W. W., Ogg, A. G. 1991. Biology and control of jointed goatgrass (*Aegilops cylindricum*), a review. Weed Technology 53: 3-17.

Flavell, R. B., Dart, E., Fuchs, R. L., and Fraley, R. T. 1992. Selectable marker genes: safe for plants? Bio/Technology 10:141-144.

Qualset, C. 1990. Wheat. In: Workshop on safeguards for planned introduction of transgenic corn and wheat (Eds. Giddings, L. V., Dilley, A. P., Starke, L.), pp. 3-13.

Jefferson, R. A., Kavanagh, T. A., Bevan, M. W. 1987. GUS fusions: beta-glucuronidase as a sensitive and versatile gene fusion marker in higher plants. EMBO Journal 6:3901-3907.

Klein, T. M., Arentzen, R., Lewis, P. A. Fitzpatrick-McElligott, S. 1992. Transformation of microbes, plants, and animals by particle bombardment. Bio/Technology 10:286-291.

OR120018_BR_011578

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OR120018_BR_011579

APPENDIX A - Permit with Standard and Supplemental Conditions

1. Permit: APHIS Form 2000 (2 pages)
2. Standard Permit Conditions
3. Supplemental Permit Conditions

OR120018_BR_011580

Supplemental Permit Conditions

Permit Number 94-024-01

1. Biotechnology, Biologics, and Environmental Protection (BBEP) or a Regional Biotechnologist will conduct an inspection of the test site at the beginning of the test. The permittee is required to notify the State regulatory official, and the appropriate Regional Biotechnologist (see attached map) at least 1-week before the test begins.

2. Additional inspections may be conducted by the Regional Biotechnologist. The permittee is required to notify the Regional Biotechnologist at least 1-week before termination of the experiment.

3. **A field test data report must be submitted within 12 months after the permit issuance date. If a field test is still in progress at 12 months or any multiple of 12 months after the permit issuance date, additional field test data reports must be submitted to APHIS within subsequent 12 month periods. Final reports for those field tests lasting more than 12 months must be submitted to APHIS 6 months after the termination of the field test.** Field test reports shall include: methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment. We encourage the inclusion of other types of data if the applicant anticipates submission of a petition for determination of regulatory status for their regulated article. APHIS views these data reports as critical to our assessment of plant pest risk and development of regulatory policies based on the best scientific evidence. Failure by an applicant to provide data reports in a timely manner for a field trial may result in the withholding of permission by APHIS for future field trials.

Confidential Business Information (CBI) will be handled according to the APHIS policy statement at 50 FR 38561-63.

4. The test site shall be monitored for any volunteer plants after the completion of the test until the end of the following growing season for wheat in the area.

5. BBEP should be notified of any proposed changes to the protocol given in the permit application.

6. This approved Biotechnology Permit (APHIS form #2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (1) for the use of any non-genetically engineered plant pest or pathogens as challenge inoculum; (2) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (3) experimental use of unregistered chemical; and (4) food or feed use of genetically engineered crops harvested from the field experiment.

OR120018_BR_011581

8/09/94 3:51 pm Release Gene Data Entry Tracking Sheet

FILE COPY

CURRENT IN DATABASE

Bp number: 94-221-01r	Intro type: Release	Renewal Permit:	Received:	8/09/94
Clock stop:	Clock start:	Due: 12/09/94	Issue/deny:	
Institution: Monsanto		Resp person: (b) (6), (b) (7)(C)		
Recipient: Wheat				
Status: Pending	Sites: 1	Acre: 1.50	Reviewer: MB SG	CBI status: CBI
Location: AZ				
Comments:				

Category:	MG
Phenotype:	PV-TXCT01, PV-TXCT02, PV-TXCT04, PV-TXCT05

SM?:	Gene:	Donor:
SM		

Reviewer of this sheet: DH JW KR SG SK SS VM

PREVIOUS ENTRIES FOR GENES AND DONORS

Category:

AP BR FR HT IR MG NR OO PQ VR

Gene:

(b) (4)

OR120018_BR_011582

FILE COPY

APPLICATION NUMBER	APPLICANT	DATE RECEIVED	ORGANISMS	FIELD TEST LOCATION
94-221-01	Monsanto Agricultural Company	8/09/94	Wheat plants genetically engineered to express marker genes.	Arizona

8/23/94

OR120018_BR_011583

FILE COPY

APPLICATION NUMBER	APPLICANT	DATE RECEIVED	ORGANISMS	FIELD TEST LOCATION
94-217-02	Monsanto Agricultural Company	8/05/94	Potato plants genetically engineered to express a gene from Bacillus thuringiensis (Btt) for resistance to coleopteran insects, and express a gene for resistance to potato leaf roll virus.	California, Florida
SG 94-221-01	Monsanto Agricultural Company	8/09/94	Wheat plants genetically engineered to express marker genes.	Arizona

8/19/94

OR120018_BR_011584

APPLICATION NUMBER	APPLICANT	DATE RECEIVED	ORGANISMS	FIELD TEST LOCATION
94-221-01	Monsanto Agricultural Company	8/09/94	Wheat plants genetically engineered to express marker genes.	Arizona

OR120018_BR_011585

APPLICATION NUMBER	APPLICANT	DATE RECEIVED	ORGANISMS	FIELD TEST LOCATION
94-221-01	Monsanto Agricultural Company	8/09/94	Wheat plants genetically engineered to express marker genes.	Arizona

OR120018_BR_011586

APPLICATION NUMBER	APPLICANT	DATE RECEIVED	ORGANISMS	FIELD TEST LOCATION
94-221-01	Monsanto Agricultural Company	8/09/94	Wheat plants genetically engineered to express marker genes.	Arizona

OR120018_BR_011587

CONTAINS C B I

...s application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq. and the Plant Quarantine Act (7 U.S.C. 151 et seq.)). The information will be used to determine eligibility to receive all types of permits. No permit shall be issued until this application has been approved.

See reverse side for additional information

FORM APPROVED
OMB NO. 0579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

94-163PR

(Genetically Engineered Organisms or Products)

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

NAME AND ADDRESS OF APPLICANT

(b) (6), (b) (7)(C)
Monsanto Agricultural Company BB3A
700 Chesterfield Parkway North, St. Louis, MO 63198

Area Code (b) (6), (b) (7)(C)

TELEPHONE NUMBER

(b) (6), (b) (7)(C)

2. PERMIT REQUESTED ("X" one)

- [ ] Limited - Interstate Movement
- [ ] Limited - Importation
- [X] Release into the Environment
- [ ] Courtesy Permit

3. THIS REQUEST IS ("X" one)

- [X] New
- [ ] Renewal
- [ ] Supplemental

5. MEANS OF MOVEMENT

- [X] Mail
- [ ] Baggage or Handcarried
- [X] Common Carrier

By whom _____

GIVE THE FOLLOWING *(if applicable) (if more space is needed, attach additional sheet)*

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism	See Attached			
b. Recipient Organism				
c. Vector or Vector Agent				
d. Regulated Organism or Product				
e. If product, list names of constituents				

QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS

See Attached

8. DATE *(or inclusive dates of period)* **OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE**

December 1, 1994 - July, 1995

COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

See Attached

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

See Attached

ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* **ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT**

None

APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

N/A

SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON	15. PRINTED NAME AND TITLE	16. DATE
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	8/5/94

FOR APHIS USE ONLY

Date Notification Sent	State Review Received	Permit Issued
August 31, 1994	September 20, 1994	[XX] Yes [ ] No

Date of Determination	Permit No.	No. of Permit Labels Issued	Supplemental Conditions Enclosed
October 21, 1994	94-221-01	n/a	[XX] Yes [ ] No

Signature of APHIS Official	Date	Expiration Date
(b) (6), (b) (7)(C) (b) (6), (b) (7)(C) Arnold Foudin, Deputy Director, BP	OCT 27 1994	OCT 27 1995

OR120018_BR_011588

CONTAINS C B I

	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article	X	
b	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e g , morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics)	X	
c	A detailed description of the molecular biology of the system (e g , donor-recipient-vector) which is or will be used to produce the regulated article	X	
d	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced	X	
e	A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design	X	
f	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the donor organism, recipient organism, vector or vector agent, constituent of each regulated article which is a product, and regulated article	X	
g	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e g greenhouses, laboratory, or growth chamber location, field trial location, pilot project location, production, propagation, and manufacture location, proposed sale and distribution location).	X	
	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.	X	
i	A detailed description of the proposed method of final disposition of the regulated article	X	

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

OR120018_BR_011589

Notice

Confidential Business Information

Some information in the attached material may be entitled to treatment as trade secret or proprietary data under Section(b)(4) of the Freedom of Information Act (FOIA) [5 U.S.C. 552(b)(4)].

Any person handling or using the attached data in any way is responsible for preventing unauthorized disclosure during possession.

Maintain this document under secure conditions.

Return to the Document Control Officer after use.

This application deals with:

MONSANTO - Wheat - MON 71 02

Identification Number:

94-221-01R

The attached information is not to be published, reproduced, publicly discussed, included in response to a FOIA request, or otherwise released without the explicit written authorization of the appropriate division director or designee.

Please disqualify yourself if there is any potential Conflict of Interest

OR120018_BR_011590

94-221-01R

CONTAINS C B I

INFORMATION SUBMITTED TO THE UNITED STATES DEPARTMENT OF AGRICULTURE IN SUPPORT OF AN APPLICATION TO FIELD TEST

TESTING OF MARKER GENES IN GENETICALLY ENGINEERED WHEAT PLANTS

94-163PR

August 5, 1994

Volume 1 of 1

Report Compiled by:
(b) (6), (b) (7)(C)

Contains Confidential Business Information (CBI)

MONSANTO AGRICULTURAL COMPANY
700 Chesterfield Parkway North • St. Louis • Missouri • 63198

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OR120018_BR_011592

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TABLE OF CONTENTS

	page
VOLUME 1	
APHIS FORM 2000	
APHIS FORM 2000 ATTACHMENTS	1

OR120018_BR_011593

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (IOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (IOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

OR120018_BR_011594

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.[1]

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of marker genes in plants and their use in insect and virus resistant and herbicide tolerant crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

1 In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011595

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Calgene, Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

OR120018_BR_011596

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for wheat has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

OR120018_BR_011597

ATTACHMENT
CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION
MARKER GENES IN WHEAT

Page	Category of Information	Justification
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011598

4	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011599

7	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011600

10	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011601

APHIS FORM 2000 ATTACHMENTS

This request for a Release into the Environment Permit is to allow the field testing of marker genes in genetically modified wheat at the locations specified in item 10. All of the information required to support this application is found in this volume.

The vector constructs that may be a part of this field experiment are:

PV-TXCT01, PV-TXCT02, PV-TXCT04, and PV-TXCT05

Item 6. The following is the information required to identify the donor, recipient, and regulated organisms and vector agent:

a) For Cotransformation Event PV-TXCT01:

Plasmid vector PV-TXGT01:

		Scientific Name	Common Name
CBI CBI CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM01:

		Scientific Name	Common Name
CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

CONTAINS C B I

b) For Cotransformation Event PV-TXCT02:

Plasmid vector PV-TXGT02:

		Scientific Name	Common Name
CBI CBI CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM02:

		Scientific Name	Common Name
CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

c) For Cotransformation Event PV-TXCT04:

Plasmid vector PV-TXSM04:

		Scientific Name	Common Name
	a. Donor Organism	TN5	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

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Plasmid vector PV-TXSM01:

		Scientific Name	Common Name
CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

d) For Cotransformation Event PV-TXCT05:

Plasmid vector PV-TXSM04:

	Scientific Name	Common Name
a. Donor Organism	TN5	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM05

	Scientific Name	Common Name
a. Donor Organism	*Zea mays*	corn
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

OR120018_BR_011604

CONSTRUCT DESCRIPTION FOR PV-TXCT01

In this instance, PV-TXGT01 AND TXSM01 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT01

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**(b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI (b) (4)

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants

CBI (b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXCT01 (Contin.)

CBI **CMoVa/**(b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI (b) (4)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.

CBI (b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**(b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI (b) (4)

TMG1 The expression of this gene is used as a marker for plant transformation.

CBI (b) (4)

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CONSTRUCT DESCRIPTION FOR PV-TXCT01 (Contin.)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011607

CONSTRUCT DESCRIPTION FOR PV-TXCT02

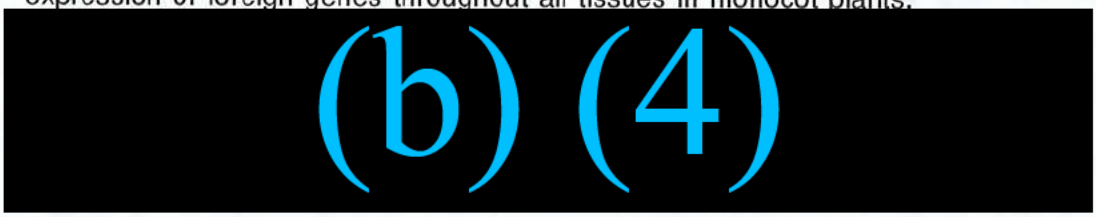
In this instance, PV-TXGT02 AND TXSM02 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT02

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMP1/**(b) (4) The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI



CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.

CBI



NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI **CMP1/**(b) (4) The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI



OR120018_BR_011608

CONSTRUCT DESCRIPTION FOR PV-TXCT02 (Contin.)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.

CBI



NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM02

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

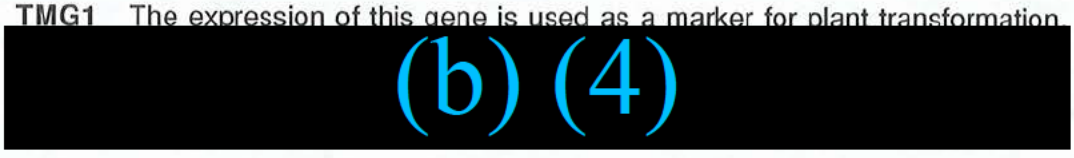
CBI **CMP1/**(b) (4) The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI



TMG1 The expression of this gene is used as a marker for plant transformation.

CBI



NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011609

CONSTRUCT DESCRIPTION FOR PV-TXCT04

In this instance, PV-TXSM04 AND TXSM01 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 gene (the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[(b) (4)] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [(b) (4)]

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011610

CONSTRUCT DESCRIPTION FOR PV-TXCT04 (Contin.)

CONSTRUCT DESCRIPTION FOR PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[redacted] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [redacted]

TMG1 The expression of this gene is used as a marker for plant transformation

CBI [redacted]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011611

CONSTRUCT DESCRIPTION FOR PV-TXCT05

In this instance, PV-TXSM04 AND TXSM05 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 gene (the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[redacted] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [redacted]

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011612

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXSM05

This construct is a free delivery: pUC-Amp vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

35S The 0.35 Kb cauliflower mosaic virus (CaMV) 35S promoter region (Odell et al. 1985, Nature 313:810-812; Gardner, et al. 1981, NAR. 9 (12):2871-2898; and Sanders, et al. 1987, NAR 15:1543-1558).

Bperu Expression of this gene will activate the pathway for anthocyanin biosynthesis in plants of the appropriate genetic background. The B gene is a 2.0 Kb cDNA sequence from Zea maize (Chandler V.L.et al. 1989. Plant Cell 1: 1175-1183).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

35S The 0.35 Kb cauliflower mosaic virus (CaMV) 35S promoter region (Odell et al. 1985, Nature 313:810-812; Gardner, et al. 1981, NAR. 9 (12):2871-2898; and Sanders, et al. 1987, NAR 15:1543-1558).

C1 Expression of this gene will activate the pathway for anthocyanin biosynthesis in plants of the appropriate genetic background. The C1 gene is a 1.1 Kb cDNA sequence from Zea maize (Pas-Arez, J. et al. 1987. EMBO 6:3553-3555).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011613

CONTAINS C B I

Item 9: The donor, recipient and vector organisms were collected in the United States. The vector construct and transgenic wheat were developed by Monsanto at the Chesterfield Village Laboratories. The planting material will be wheat seeds produced by and shipped from:

(b) (6), (b) (7)(C)
The Agricultural Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
Tel.: (b) (6), (b) (7)(C)
Fax: 314-537-6950

Item 10. The locations of the field experiment is as follows:

Somerton, Arizona
Yuma County

Principle Investigator: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) Arizona (b) (4), (b) (6), (b) (7)(C)
Ph.: (b) (4), (b) (6), (b) (7)(C)
Fax: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Item 13a. The transgenic wheat which is the subject of this permit request, was developed by scientists at Monsanto. For additional information contact the applicant of this permit.

Item 13b. The transgenic material that is the recipient of the added genes is the CIMMYT(Centro Internaclonal de Mejoramiento de Maiz y Trigo, Facimile 52-595-41069) line Bobwhite. The line Bobwhite was designated to a group of advanced lines derived from the cross Aurora/Kalyan/Bluebird/3/Woodpecker CM33203. This cross was made at CIMMYT in 1973.

Bobwhite is in general semidwarf, carries resistance to septoria tritici, leaf rust, and the gene YR9 for stripe rust. The Bobwhite lines carry the 1B/1R translocation i.e. 1BS is translocated by 1RS of rye. The 1B/1R was derived from the variety Aurora from the USSR. Despite the fact that it carries 1B/1R translocation associated with poor quality(stickiness), industrial quality of Bobwhite is good, and acceptable in most countries.

The Bobwhite line has been genetically -modified by particle bombardment for co-transformation of one of the scorable or selectable markers described . At present no molecular or segregation data is available from the lines that will be evaluated in the field trial. However the original transformed plants have been qualitatively evaluated for gene expression of the selectable marker/s with positive results.

OR120018_BR_011614

CONTAINS C B I

Item 13c. The description of the plasmid vector as inserted into these wheat plants is described below.

VECTOR DESCRIPTION FOR FREE DELIVERY

Free delivery vectors are engineered to contain multiple chimeric plant expression genes in either the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11) or pMON 10081, a derivative of the high copy *E. coli* plasmid pUC119. These vectors contain either the B-lactamase gene conferring bacterial ampicillin resistance (pUC119) or the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance (pMON 10081). The antibiotic markers are driven by bacterial promoters which do not contain the regulatory elements necessary to express in plants. They are also used to propagate the plasmid in *E. coli* in order to produce sufficient DNA quantities for transformation experiments (further described in Delivery System Description).

FREE DELIVERY PARTICLE GUN (MONSANTO)

Introduction of DNA into plant tissue with the "biolistic" particle bombardment method has been described in detail by Klein et al. (1987, Nature 327: 70-73; 1988a, Bio/Technology 6: 559-563; and 1988b, Proc Natl Acad Sci USA 85: 4305-4309). The transgenic material in this application was produced using the commercially available PDS1000 particle delivery system (originally leased from DuPont, now available through Bio-Rad Laboratories). Detailed instructions are available from the manufacturers. Briefly, DNA is precipitated onto microscopic (~1 μ diameter) tungsten or gold particles using calcium chloride and spermidine. A drop (2.5μl) of the coated particles is then placed onto a plastic macrocarrier, which is accelerated at a high velocity through a barrel by the explosive force of a gunpowder discharge. The macrocarrier hits a plastic "stopping plate" which stops the flight of the macrocarrier but allows continued flight of the DNA-coated particles. The particles penetrate the target plant cells, where the DNA is deposited and incorporated into the plant cell genome. The cells are incubated on a tissue culture medium which supports the growth of embryogenic callus. The introduced DNA contains a gene(s) encoding for resistance to either antibiotics (e.g., the NPTII gene for resistance to kanamycin and G418) or genes conferring resistance to glyphosate. The plant cells are grown in the presence of an appropriate antibiotic or glyphosate, and only the transformed cells continue grow. Plants are regenerated from the resistant embryogenic callus tissue, and are assayed for the presence of the introduced gene(s). The free delivery vectors are engineered to contain multiple chimeric plant expression genes in the high copy E. coli plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). The pUC119 plasmid contains the ß-lactamase gene conferring bacterial ampicillin resistance. Several chimeric plant expression genes can be introduced into pUC119. These include the marker genes required for selection of the transformed plant tissue, and one or more genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

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CONTAINS C B I

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Amp

The free delivery vectors are engineered to contain multiple chimeric plant expression genes in the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). The pUC119 plasmid contains the ß-lactamase gene conferring bacterial ampicillin resistance. Several chimeric plant expression genes can be introduced into pUC119. These include the marker genes required for selection of the transformed plant tissue, and one or more genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Kan

The free delivery vectors contain multiple chimeric plant expression genes engineered into pMON10081. The pMON10081 plasmid is a derivative of the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). It was constructed by fusing the 1.3 Kb FspI-DraI origin of replication fragment from pUC119, to the 1.3 Kb SmaI-HindIII (Klenow filled) fragment from pKC7 (Rao and Rogers 1979, Gene 7: 79). The pKC7 fragment contains the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance. The ß-lactamase gene conferring bacterial ampicillin resistance was completely deleted. Several chimeric plant expression genes can be introduced into pMON10081. These include the marker genes required for selection of the transformed plant tissue, and one or more chimeric genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

Item 13d. The plasmid vectors were constructed at the research laboratories of Monsanto Co. in St. Louis, Missouri. The initial wheat plants transformed with these vectors were also developed at the research laboratories of Monsanto Co. in St. Louis, Missouri, USA.

Item 13e. The information regarding the description of the propose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design is found in the following protocol:

PROPOSED EXPERIMENTAL PROGRAM

MARKER GENES IN GENETICALLY MODIFIED WHEAT

Purpose of the test:

To test the efficacy of various marker genes in wheat.

Investigators:

* Principal Monsanto investigator at St. Louis, MO:

(b) (6), (b) (7)(C)
The Agriculture Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
phone: (b) (6), (b) (7)(C)
FAX: (314) 537-6950

* Principal investigator at field site:

Principle Investigator:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) Arizona (b) (4), (b) (6), (b) (7)(C)
Ph.: (b) (4), (b) (6), (b) (7)(C)
Fax: (b) (4), (b) (6), (b) (7)(C)

Mr. Wagner can be reached prior to October 1 at the Moses Lake, Washington facility at (509) 765-4937.

CONTAINS C B I

Field Test Design:

* The test will use an experimental design that best addresses the test objectives while dealing with limited seed quantities.

* Treatments will be chosen from the following:

    * Chemical herbicide: Use of commercially available herbicides or proprietary chemistry to evaluate the effects of application on weed control and crop tolerance.

    * Timing of application: Chosen from growth stages between emergence through first flowering including sequential applications at two or more growth stages.

    * Type of application: Over-the-top or post-directed.

Genotypes:

* Homozygous and segregating progeny of lines transformed with one of the following vectors:

  PV-TXCT01
  PV-TXCT02
  PV-TXCT04
  PV-TXCT05

* Non-transgenic Bobwhite.

Plot design:

* Each plot will consist of one to four rows, 4-12 inches apart and up to 20 feet long.

* A standard experimental design will be utilized such as a randomized complete block design or a split plot design.

* The number of replications will be determined by seed availability.
  The anticipated number of replications is from one to four.

Space requirements:

* The transgenic material will cover less than 1.0 acre with no more than 500,000 plants.

* The experiment including the border will cover less than 1.2 acres.

* The total area needed for the entire test (including borders and alleyways) will be no greater than 1.5 acres.

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CONTAINS C B I

Isolation:

This trial will be isolated from other wheat according to the standards set forth by Association of Official Seed Certifying Agencies in the "Certification Handbook." In using these guidelines for reference, the wheat in this trial will be separated from other wheat by a 20 foot strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat.

Tentative schedule:

* Planting: November 1 to February 1 depending on weather and seed availability.

* Harvest: April 1 to July 1 depending on weather and date of planting.

Agronomic practices:

* Ground preparation and fertility: Ground preparation will follow normal practices for wheat. Fertilizer may be applied based on a soil test to bring the nutrient level up to that recommended for wheat. Additional fertilizer may be applied throughout the season as needed.

* Weed control: Weed control will follow acceptable practices for wheat by using labelled herbicides, experimental herbicides, and/or hand weeding.

* Disease control: Diseases will be controlled by the use of labelled fungicides for seed treatment and/or topical applications.

* Insect control: Insect pests will be monitored for their appearance in the field. Insecticides labelled to control insect pests that are present will be applied as needed, including seed treatments or topical applications.

Harvest procedures:

* The wheat will be harvested by hand or with a field plot harvester. If a machine is used, it will be thoroughly cleaned prior to exiting the plot area.

Plant and seed disposal:

* Some seed will be sent to Monsanto laboratories in Chesterfield, MO for further analysis. After data collection and harvest, all remaining seed not sent to Monsanto will be either clearly marked and stored in a secure facility at the site or destroyed on the site by distribution in the field. The seed and remaining plant stubble will be mechanically incorporated into the soil. After the experiment is concluded, the plot area will be monitored for 8 months for germinating seed which will be destroyed with tillage or herbicide treatment.

OR120018_BR_011619

CONTAINS C B I

SITE SPECIFIC INFORMATION

(b) (4) Arizona
Yuma County

Principle Investigator: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) Arizona (b) (4), (b) (6), (b) (7)(C)
Ph.: (b) (4), (b) (6), (b) (7)(C)
Fax: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C)

Site Description: The immediate area surrounding the plot consists of small research plots for the seed material increase of spring barley, spring and winter wheat, crambe, and dry beans. The surrounding agricultural area is established in the production of produce, predominantly lettuce. The geographical region is arid with large volumes of supplemental irrigation.

Item 13f. All research and procedures used in the production of the donor organism, recipient organism, vector or vector agent and the transgenic wheat were done utilizing level BL2 containment according to the NIH Guidelines for Recombinant DNA Research. All transgenic plants and their clonally propagated "progeny" have been repeatedly tested, and do not contain *Agrobacterium* cells.

Items 13g and h: None of the wheat seed or plant material produced in this experiment will enter commerce or will be consumed by domestic animals.

Seed will be taken to the field sites in containers fastened to preclude spillage. Movement will be in an enclosed vehicle. Up to three movements to each field site are anticipated. There will be up to 20 pounds of seed totaled over the three movements to each site. Movements should occur from November 1 - February 1, 1993.

Isolation:

This trial will be isolated from other wheat according to the standards set forth by Association of Official Seed Certifying Agencies in the "Certification Handbook." In using these guidelines for reference, the wheat in this trial will be separated from other wheat by a 20 foot strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat.

Harvest:

Plots will be harvested, either by hand or by machine. If a machine is used, it will be thoroughly cleaned prior to exiting the plot area.

CONTAINS C B I

Item 13i. Following harvest, some seed will be sent to Monsanto laboratories in Chesterfield, Missouri for further analysis. After data collection and harvest, all remaining seed not sent to Monsanto will be either clearly marked and stored in a secure facility on site or destroyed on the site by distribution in the field. The seed and remaining plant stubble will be mechanically incorporated into the soil.

After the experiment is concluded, the plot area will be monitored for eight months for plants. Any such volunteers will be killed through cultivation and/or herbicide treatment.

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94-221-01R

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (IOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (IOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

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The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.[1]

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of marker genes in plants and their use in insect and virus resistant and herbicide tolerant crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

1 In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011623

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Calgene, Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

OR120018_BR_011624

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for wheat has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

OR120018_BR_011625

ATTACHMENT
CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION
MARKER GENES IN WHEAT

Page	Category of Information	Justification
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
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1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
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2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011626

4	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
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5	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

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7	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
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9	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011628

10	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

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CBI DELETED

...s application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq. and the Plant ... U.S.C. 151 et seq.). The information will be used to determine eligibility to receive all types of p... permit shall be issued until this application has been approved.

94-221-01r

...reverse side for ...itional information

FORM APPROVED
OMB NO. 0579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNO... OGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

94-163PR

(Genetically Engineered Organisms or Products)

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

NAME AND ADDRESS OF APPLICANT

(b) (6), (b) (7)(C)
Monsanto Agricultural Company BB3A
700 Chesterfield Parkway North, St. Louis, MO 63198

Area Code (314) 537-7488

TELEPHONE NUMBER

(314) 537-7488

2. PERMIT REQUESTED ("X" one)

- [ ] Limited - Interstate Movement
- [ ] Limited - Importation
- [X] Release into the Environment
- [ ] Courtesy Permit

3. THIS REQUEST IS ("X" one)

- [X] New
- [ ] Renewal
- [ ] Supplemental

5. MEANS OF MOVEMENT

- [X] Mail
- [ ] Baggage or Handcarried
- [X] Common Carrier

By whom _____

GIVE THE FOLLOWING *(if applicable) (if more space is needed, attach additional sheet)*

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism	See Attached			
b. Recipient Organism				
c. Vector or Vector Agent				
d. Regulated Organism or Product				
e. If product, list names of constituents				

QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS

See Attached

8. DATE *(or inclusive dates of period)* **OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE**

December 1, 1994 - July, 1995

COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

See Attached

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

See Attached

ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* **ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT**

None

APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

N/A

. SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

SIGNATURE OF RESPONSIBLE PERSON	15. PRINTED NAME AND TITLE	16. DATE
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	8/5/94

FOR APHIS USE ONLY

...te Notification Sent	State Review Received	Permit Issued
August 31, 1994	September 20, 1994	[X] Yes [ ] No

...te of Determination	Permit No.	No. of Permit Labels Issued	Supplemental Conditions Enclosed
October 21, 1994	94-221-01	n/a	[X] Yes [ ] No

...nature of APHIS Official

(b) (6), (b) (7)(C)

(b) (6), (b) (7)(C) for Arnold Foudin, Deputy Director, BP

OR120018_BR_011630

Date: OCT 27 1994

Expiration Date: OCT 27 1995

CBI DELETED

	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article	X	
b	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e g , morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics)	X	
c	A detailed description of the molecular biology of the system (e g , donor-recipient-vector) which is or will be used to produce the regulated article	X	
d	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced	X	
e	A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design.	X	
f	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the donor organism, recipient organism, vector or vector agent; constituent of each regulated article which is a product, and regulated article	X	
g	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e g greenhouses, laboratory, or growth chamber location, field trial location, pilot project location, production, propagation, and manufacture location, proposed sale and distribution location).	X	
	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.	X	
i	A detailed description of the proposed method of final disposition of the regulated article	X	

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

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Monsanto

94-221-01r

CBI-deleted

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

August 5, 1994

Att: E.Dianne Hatmaker
Cheif, Permits Branch
Biotechnology Permits
Biotechnology, Biologics, and Environmental Protection
6505 Belcrest Rd, Suite 7
Hyattsville, MD 20782
FAX: 301-436-8910

Subject: Request for a Permit to Field Test
Marker Genes in Wheat

Dear Ms. Hatmaker:

Monsanto Agricultural Company is requesting a permit from USDA to allow wheat which has been genetically modified for the expression of marker genes to be tested in Arizona.

In support of this request for a permit to allow release into the environment, please find the completed APHIS Form 2000 attached to this letter. In addition we are submitting 1 copy of the application containing the required information to support this request. This volume contains confidential business information (CBI) and is so marked on the cover and each place within the volume where the CBI occurs. As required, we are also submitting 1 copy of this same material with all CBI deleted.

This confidential information was developed by Monsanto at its own expense, has not been released to anyone not under a secrecy agreement to Monsanto and has not been published. We request that this information not be released as it has value to our competitors (domestic and foreign) in that they would be able to copy this work and unfairly compete with us causing financial loss and other harm to Monsanto.

We appreciate your attention to this matter. Should you have any questions, please feel free to contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

OR120018_BR_011632

CBI DELETED

INFORMATION SUBMITTED TO THE UNITED STATES DEPARTMENT OF AGRICULTURE IN SUPPORT OF AN APPLICATION TO FIELD TEST

TESTING OF MARKER GENES IN GENETICALLY ENGINEERED WHEAT PLANTS

94-163PR

August 5, 1994

Volume 1 of 1

Report Compiled by:
(b) (6), (b) (7)(C)

Contains Confidential Business Information (CBI)

MONSANTO AGRICULTURAL COMPANY
700 Chesterfield Parkway North • St. Louis • Missouri • 63198

OR120018_BR_011633

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State of Arizona	-	1 Copy
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REGISTRATION FILES	1 Copy	1 Copy

OR120018_BR_011634

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TABLE OF CONTENTS

page

VOLUME 1

APHIS FORM 2000

APHIS FORM 2000 ATTACHMENTS 1

CBI DELETED

...s application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq. and the Plant ... U.S.C. 151 et seq.). The information will be used to determine eligibility to receive all types of p... permit shall be issued until this application has been approved.

94-221-01r

...reverse side for ...litional information

FORM APPROVED
OMB NO. 0579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

94-163PR

(Genetically Engineered Organisms or Products)

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

NAME AND ADDRESS OF APPLICANT

(b) (6), (b) (7)(C)
Monsanto Agricultural Company BB3A
700 Chesterfield Parkway North, St. Louis, MO 63198

Area Code ((b) (6), (b) (7)(C)

TELEPHONE NUMBER

(b) (6), (b) (7)(C)

2. PERMIT REQUESTED ("X" one)

- [ ] Limited - Interstate Movement
- [ ] Limited - Importation
- [X] Release into the Environment
- [ ] Courtesy Permit

3. THIS REQUEST IS *("X" one)*

- [X] New
- [ ] Renewal
- [ ] Supplemental

5. MEANS OF MOVEMENT

- [X] Mail
- [ ] Baggage or Handcarried
- [X] Common Carrier
- By whom _____

GIVE THE FOLLOWING *(if applicable) (if more space is needed, attach additional sheet)*

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism	See Attached			
b. Recipient Organism				
c. Vector or Vector Agent				
d. Regulated Organism or Product				
e. If product, list names of constituents				

QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS

See Attached

8. DATE *(or inclusive dates of period)* OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE

December 1, 1994 - July, 1995

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See Attached

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

See Attached

ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* **ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT**

None

APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

N/A

. SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

SIGNATURE OF RESPONSIBLE PERSON	15. PRINTED NAME AND TITLE	16. DATE
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	8/5/94

FOR APHIS USE ONLY

...te Notification Sent	State Review Received	Permit Issued
		[ ] Yes [ ] No

...te of Determination	Permit No.	No. of Permit Labels Issued	Supplemental Conditions Enclosed
			[ ] Yes [ ] No

...nature of BBEP Official	Date	Expiration Date

OR120018_BR_011636

CBI DELETED

	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article	X	
b	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics)	X	
c	A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article	X	
d	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced	X	
e	A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design.	X	
f	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: donor organism, recipient organism, vector or vector agent; constituent of each regulated article which is a product, and regulated article	X	
g	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location, field trial location, pilot project location, production, propagation, and manufacture location, proposed sale and distribution location).	X	
	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.	X	
i	A detailed description of the proposed method of final disposition of the regulated article	X	

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

OR120018_BR_011637

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (IOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (IOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.[1]

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of marker genes in plants and their use in insect and virus resistant and herbicide tolerant crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

1 In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011639

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Calgene, Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

OR120018_BR_011640

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for wheat has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

OR120018_BR_011641

ATTACHMENT
CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION
MARKER GENES IN WHEAT

Page	Category of Information	Justification
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011642

4	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011643

7	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011644

1 0	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1 1	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1 1	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

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APHIS FORM 2000 ATTACHMENTS

This request for a Release into the Environment Permit is to allow the field testing of marker genes in genetically modified wheat at the locations specified in item 10. All of the information required to support this application is found in this volume.

The vector constructs that may be a part of this field experiment are:

PV-TXCT01, PV-TXCT02, PV-TXCT04, and PV-TXCT05

Item 6. The following is the information required to identify the donor, recipient, and regulated organisms and vector agent:

a) For Cotransformation Event PV-TXCT01:

Plasmid vector PV-TXGT01:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] [CBI DELETED] [CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM01:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

CBI DELETED

b) For Cotransformation Event PV-TXCT02:

Plasmid vector PV-TXGT02:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] [CBI DELETED] [CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM02:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

c) For Cotransformation Event PV-TXCT04:

Plasmid vector PV-TXSM04:

	Scientific Name	Common Name
a. Donor Organism	TN5	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

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Plasmid vector PV-TXSM01:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

d) **For Cotransformation Event PV-TXCT05:**

Plasmid vector PV-TXSM04:

	Scientific Name	Common Name
a. Donor Organism	TN5	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM05

	Scientific Name	Common Name
a. Donor Organism	*Zea mays*	corn
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

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CONSTRUCT DESCRIPTION FOR PV-TXCT01

In this instance, PV-TXGT01 AND TXSM01 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT01

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
[

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]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.
[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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CONSTRUCT DESCRIPTION FOR PV-TXCT01 (Contin.)

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
[

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]

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.
[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
[

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]

TMG1 The expression of this gene is used as a marker for plant transformation.
[

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]

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CONSTRUCT DESCRIPTION FOR PV-TXCT01 (Contin.)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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CONSTRUCT DESCRIPTION FOR PV-TXCT02

In this instance, PV-TXGT02 AND TXSM02 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXGT02

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMP1/[ ] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

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CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.
[

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]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMP1/[ ] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

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CONSTRUCT DESCRIPTION FOR PV-TXCT02 (Contin.)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.

CBI [

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NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM02

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMP1/[ ] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

[

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]

TMG1 The expression of this gene is used as a marker for plant transformation.

[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT04

In this instance, PV-TXSM04 AND TXSM01 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 gene (the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

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]

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
[

CBI DELETED

]

TMG1 The expression of this gene is used as a marker for plant transformation.
[

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]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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CONSTRUCT DESCRIPTION FOR PV-TXCT05

In this instance, PV-TXSM04 AND TXSM05 were present on separate plasmids, but were introduced into the same plant through a process termed co-transformation. The result is that at a high frequency the different plasmid molecules integrate into the genome of the same plant cell. Generally the integration is into the same chromosomal location in the plant cell, presumably due to recombination of the plasmids prior to integration. Less frequently, the different plasmids integrate into separate chromosomal locations. In either case, there is integration of both DNA molecules into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 gene (the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
[

CBI DELETED

]

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM05

This construct is a free delivery: pUC-Amp vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

35S The 0.35 Kb cauliflower mosaic virus (CaMV) 35S promoter region (Odell et al. 1985, Nature 313:810-812; Gardner, et al. 1981, NAR. 9 (12):2871-2898; and Sanders, et al. 1987, NAR 15:1543-1558).

Bperu Expression of this gene will activate the pathway for anthocyanin biosynthesis in plants of the appropriate genetic background. The B gene is a 2.0 Kb cDNA sequence from Zea maize (Chandler V.L.et al. 1989. Plant Cell 1: 1175-1183).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

35S The 0.35 Kb cauliflower mosaic virus (CaMV) 35S promoter region (Odell et al. 1985, Nature 313:810-812; Gardner, et al. 1981, NAR. 9 (12):2871-2898; and Sanders, et al. 1987, NAR 15:1543-1558).

C1 Expression of this gene will activate the pathway for anthocyanin biosynthesis in plants of the appropriate genetic background. The C1 gene is a 1.1 Kb cDNA sequence from Zea maize (Pas-Arez, J. et al. 1987. EMBO 6:3553-3555).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

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Item 9: The donor, recipient and vector organisms were collected in the United States. The vector construct and transgenic wheat were developed by Monsanto at the Chesterfield Village Laboratories. The planting material will be wheat seeds produced by and shipped from:

(b) (6), (b) (7)(C)
The Agricultural Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
Tel.: (b) (6), (b) (7)(C)
Fax: 314-537-6950

Item 10. The locations of the field experiment is as follows:

Somerton, Arizona
Yuma County

Principle Investigator: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) Arizona (b) (6), (b) (7)(C), (b) (4)
Ph.: (b) (6), (b) (7)(C), (b) (4)
Fax:

(b) (6), (b) (7)(C), (b) (4)

Item 13a. The transgenic wheat which is the subject of this permit request, was developed by scientists at Monsanto. For additional information contact the applicant of this permit.

Item 13b. The transgenic material that is the recipient of the added genes is the CIMMYT(Centro Internaclonal de Mejoramiento de Maiz y Trigo, Facimile 52-595-41069) line Bobwhite. The line Bobwhite was designated to a group of advanced lines derived from the cross Aurora/Kalyan/Bluebird/3/Woodpecker CM33203. This cross was made at CIMMYT in 1973.

Bobwhite is in general semidwarf, carries resistance to septoria tritici, leaf rust, and the gene YR9 for stripe rust. The Bobwhite lines carry the 1B/1R translocation i.e. 1BS is translocated by 1RS of rye. The 1B/1R was derived from the variety Aurora from the USSR. Despite the fact that it carries 1B/1R translocation associated with poor quality(stickiness), industrial quality of Bobwhite is good, and acceptable in most countries.

The Bobwhite line has been genetically -modified by particle bombardment for co-transformation of one of the scorable or selectable markers described . At present no molecular or segregation data is available from the lines that will be evaluated in the field trial. However the original transformed plants have been qualitatively evaluated for gene expression of the selectable marker/s with positive results.

CBI DELETED

Item 13c. The description of the plasmid vector as inserted into these wheat plants is described below.

VECTOR DESCRIPTION FOR FREE DELIVERY

Free delivery vectors are engineered to contain multiple chimeric plant expression genes in either the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11) or pMON 10081, a derivative of the high copy *E. coli* plasmid pUC119. These vectors contain either the B-lactamase gene conferring bacterial ampicillin resistance (pUC119) or the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance (pMON 10081). The antibiotic markers are driven by bacterial promoters which do not contain the regulatory elements necessary to express in plants. They are also used to propagate the plasmid in *E. coli* in order to produce sufficient DNA quantities for transformation experiments (further described in Delivery System Description).

FREE DELIVERY PARTICLE GUN (MONSANTO)

Introduction of DNA into plant tissue with the "biolistic" particle bombardment method has been described in detail by Klein et al. (1987, Nature 327: 70-73; 1988a, Bio/Technology 6: 559-563; and 1988b, Proc Natl Acad Sci USA 85: 4305-4309). The transgenic material in this application was produced using the commercially available PDS1000 particle delivery system (originally leased from DuPont, now available through Bio-Rad Laboratories). Detailed instructions are available from the manufacturers. Briefly, DNA is precipitated onto microscopic (~1 μ diameter) tungsten or gold particles using calcium chloride and spermidine. A drop (2.5μl) of the coated particles is then placed onto a plastic macrocarrier, which is accelerated at a high velocity through a barrel by the explosive force of a gunpowder discharge. The macrocarrier hits a plastic "stopping plate" which stops the flight of the macrocarrier but allows continued flight of the DNA-coated particles. The particles penetrate the target plant cells, where the DNA is deposited and incorporated into the plant cell genome. The cells are incubated on a tissue culture medium which supports the growth of embryogenic callus. The introduced DNA contains a gene(s) encoding for resistance to either antibiotics (e.g., the NPTII gene for resistance to kanamycin and G418) or genes conferring resistance to glyphosate. The plant cells are grown in the presence of an appropriate antibiotic or glyphosate, and only the transformed cells continue grow. Plants are regenerated from the resistant embryogenic callus tissue, and are assayed for the presence of the introduced gene(s). The free delivery vectors are engineered to contain multiple chimeric plant expression genes in the high copy E. coli plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). The pUC119 plasmid contains the ß-lactamase gene conferring bacterial ampicillin resistance. Several chimeric plant expression genes can be introduced into pUC119. These include the marker genes required for selection of the transformed plant tissue, and one or more genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

CBI DELETED

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Amp

The free delivery vectors are engineered to contain multiple chimeric plant expression genes in the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). The pUC119 plasmid contains the ß-lactamase gene conferring bacterial ampicillin resistance. Several chimeric plant expression genes can be introduced into pUC119. These include the marker genes required for selection of the transformed plant tissue, and one or more genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Kan

The free delivery vectors contain multiple chimeric plant expression genes engineered into pMON10081. The pMON10081 plasmid is a derivative of the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). It was constructed by fusing the 1.3 Kb FspI-DraI origin of replication fragment from pUC119, to the 1.3 Kb SmaI-HindIII (Klenow filled) fragment from pKC7 (Rao and Rogers 1979, Gene 7: 79). The pKC7 fragment contains the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance. The ß-lactamase gene conferring bacterial ampicillin resistance was completely deleted. Several chimeric plant expression genes can be introduced into pMON10081. These include the marker genes required for selection of the transformed plant tissue, and one or more chimeric genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

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Item 13d. The plasmid vectors were constructed at the research laboratories of Monsanto Co. in St. Louis, Missouri. The initial wheat plants transformed with these vectors were also developed at the research laboratories of Monsanto Co. in St. Louis, Missouri, USA.

Item 13e. The information regarding the description of the propose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design is found in the following protocol:

PROPOSED EXPERIMENTAL PROGRAM

MARKER GENES IN GENETICALLY MODIFIED WHEAT

Purpose of the test:

To test the efficacy of various marker genes in wheat.

Investigators:

* Principal Monsanto investigator at St. Louis, MO:

(b) (6), (b) (7)(C)
The Agriculture Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
phone: (b) (6), (b) (7)(C)
FAX: (314) 537-6950

* Principal investigator at field site:

Principle Investigator:

(b) (6), (b) (7)(C), (b) (4)
Arizona
Ph.: (b) (6), (b) (7)(C), (b) (4)
Fax:

(b) (6), (b) (7)(C), (b) (4)

CBI DELETED

Field Test Design:

* The test will use an experimental design that best addresses the test objectives while dealing with limited seed quantities.

* Treatments will be chosen from the following:

    * Chemical herbicide: Use of commercially available herbicides or proprietary chemistry to evaluate the effects of application on weed control and crop tolerance.

    * Timing of application: Chosen from growth stages between emergence through first flowering including sequential applications at two or more growth stages.

    * Type of application: Over-the-top or post-directed.

Genotypes:

* Homozygous and segregating progeny of lines transformed with one of the following vectors:

  PV-TXCT01
  PV-TXCT02
  PV-TXCT04
  PV-TXCT05

* Non-transgenic Bobwhite.

Plot design:

* Each plot will consist of one to four rows, 4-12 inches apart and up to 20 feet long.

* A standard experimental design will be utilized such as a randomized complete block design or a split plot design.

* The number of replications will be determined by seed availability.
  The anticipated number of replications is from one to four.

Space requirements:

* The transgenic material will cover less than 1.0 acre with no more than 500,000 plants.

* The experiment including the border will cover less than 1.2 acres.

* The total area needed for the entire test (including borders and alleyways) will be no greater than 1.5 acres.

CBI DELETED

Isolation:

This trial will be isolated from other wheat according to the standards set forth by Association of Official Seed Certifying Agencies in the "Certification Handbook." In using these guidelines for reference, the wheat in this trial will be separated from other wheat by a 20 foot strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat.

Tentative schedule:

* Planting: November 1 to February 1 depending on weather and seed availability.

* Harvest: April 1 to July 1 depending on weather and date of planting.

Agronomic practices:

* Ground preparation and fertility: Ground preparation will follow normal practices for wheat. Fertilizer may be applied based on a soil test to bring the nutrient level up to that recommended for wheat. Additional fertilizer may be applied throughout the season as needed.

* Weed control: Weed control will follow acceptable practices for wheat by using labelled herbicides, experimental herbicides, and/or hand weeding.

* Disease control: Diseases will be controlled by the use of labelled fungicides for seed treatment and/or topical applications.

* Insect control: Insect pests will be monitored for their appearance in the field. Insecticides labelled to control insect pests that are present will be applied as needed, including seed treatments or topical applications.

Harvest procedures:

* The wheat will be harvested by hand or with a field plot harvester. If a machine is used, it will be thoroughly cleaned prior to exiting the plot area.

Plant and seed disposal:

* Some seed will be sent to Monsanto laboratories in Chesterfield, MO for further analysis. After data collection and harvest, all remaining seed not sent to Monsanto will be either clearly marked and stored in a secure facility at the site or destroyed on the site by distribution in the field. The seed and remaining plant stubble will be mechanically incorporated into the soil. After the experiment is concluded, the plot area will be monitored for 8 months for germinating seed which will be destroyed with tillage or herbicide treatment.

CBI DELETED

SITE SPECIFIC INFORMATION

(b) (4) Arizona
Yuma County

Principle Investigator: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Arizona (b) (6), (b) (7)(C), (b) (4)
Ph.: (b) (6), (b) (7)(C), (b) (4)
Fax:

(b) (6), (b) (7)(C), (b) (4)

Site Description: The immediate area surrounding the plot consists of small research plots for the seed material increase of spring barley, spring and winter wheat, crambe, and dry beans. The surrounding agricultural area is established in the production of produce, predominantly lettuce. The geographical region is arid with large volumes of supplemental irrigation.

Item 13f. All research and procedures used in the production of the donor organism, recipient organism, vector or vector agent and the transgenic wheat were done utilizing level BL2 containment according to the NIH Guidelines for Recombinant DNA Research. All transgenic plants and their clonally propagated "progeny" have been repeatedly tested, and do not contain *Agrobacterium* cells.

Items 13g and h: None of the wheat seed or plant material produced in this experiment will enter commerce or will be consumed by domestic animals.

Seed will be taken to the field sites in containers fastened to preclude spillage. Movement will be in an enclosed vehicle. Up to three movements to each field site are anticipated. There will be up to 20 pounds of seed totaled over the three movements to each site. Movements should occur from November 1 - February 1, 1993.

Isolation:

This trial will be isolated from other wheat according to the standards set forth by Association of Official Seed Certifying Agencies in the "Certification Handbook." In using these guidelines for reference, the wheat in this trial will be separated from other wheat by a 20 foot strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat.

Harvest:

Plots will be harvested, either by hand or by machine. If a machine is used, it will be thoroughly cleaned prior to exiting the plot area.

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Item 13i. Following harvest, some seed will be sent to Monsanto laboratories in Chesterfield, Missouri for further analysis. After data collection and harvest, all remaining seed not sent to Monsanto will be either clearly marked and stored in a secure facility on site or destroyed on the site by distribution in the field. The seed and remaining plant stubble will be mechanically incorporated into the soil.

After the experiment is concluded, the plot area will be monitored for eight months for plants. Any such volunteers will be killed through cultivation and/or herbicide treatment.

OR120018_BR_011665

APHIS APPLICATION NO. 94-221-01
DATE: AUGUST 31, 1994

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

_____ State concurs with APHIS' initial review.

_____ State concurs with APHIS' initial review and offers the following comments (use additional sheets if necessary):

_____ State **does not concur** with APHIS' initial review and offers the following reasons for nonconcurrence (use additional sheets if necessary):

Name of State Official: _____

Title: _____

Agency or Department:

Address: P.O. Box 234

City, State, Zip Code: Phoenix, AZ 85007

Signature: _____

Date: _____

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

SUBHASH GUPTA
USDA, APHIS, BBEP
Biotechnology Permits, FB Room 843
6505 Belcrest Road
Hyattsville, MD 20782

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FILE COPY

APHIS APPLICATION NO. 94-221-01
DATE: AUGUST 31, 1994

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

__X__ State concurs with APHIS' initial review.

_____ State concurs with APHIS' initial review and offers the following comments (use additional sheets if necessary):

_____ State **does not concur** with APHIS' initial review and offers the following reasons for nonconcurrence (use additional sheets if necessary):

Name of State Official: Ken L. Boyd

Title: Associate Director, Plant Services Division

Agency or Department:
Arizona Department of Agriculture

Address: P.O. Box 234

City, State, Zip Code: Phoenix, AZ 85007

Signature: (b) (6), (b) (7)(C)

Date: September 7, 1994

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

SUBHASH GUPTA
USDA, APHIS, BBEP
Biotechnology Permits, FB Room 843
6505 Belcrest Road
Hyattsville, MD 20782

RECEIVED 9.20.94
#9 RP

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FILE COPY

(b) (6), (b) (7)(C)
Monsanto Agricultural Products
600 Chesterfield Village Parkway
St. Louis, MO 63198

August 19, 1994

Dear (b) (6), (b) (7)(C)

This is in response to your permit application received August 9, 1994, for release into the environment under 7 C.F.R. §340.

The application for a permit to conduct a field test of genetically engineered wheat plants that express marker genes, has been assigned application number 94-221-01 r. Please refer to this number in correspondence that pertains to this application. You will be notified by letter if further information is needed for this permit application review. The technical reviewer assigned to this application is Dr. Subhash Gupta.

A notice will be published in the Federal Register advising the public of the Animal and Plant Health Inspection Service's (APHIS) receipt of your application. The non-confidential business information copy of your application will be made available to the public through the APHIS Reading Room as specified in the Federal Register, through the Biotechnology Permits Office, and through the Freedom of Information Act Office.

Some States have separate regulations pertaining to release and movement of genetically engineered organisms, therefore it is recommended that you submit your application to the appropriate State(s) at the same time it is submitted to APHIS. This allows the States adequate time to review the application and respond promptly to APHIS' preliminary assessment.

Please call our office at Area Code (301) 436-7612 if you have questions or if we can be of assistance. Thank you for your cooperation.

Sincerely,

Clayton Givens
Program Assistant
Biotechnology Program Operations

cc:Permit application file 94-221-01r

OR120018_BR_011668

FILE COPY AUG 31 1994

Mr. Glen Thaxton
Arizona Department of Agriculture
P.O. Box 234
Phoenix, AZ 85007

Re: APHIS Preliminary Review of an Application by the Monsanto Agricultural Company to Field Test Genetically Engineered Wheat Plants. Accession Number 94-221-01.

Dear Mr. Thaxton:

This letter contains our preliminary review of an application submitted the by Monsanto Agricultural Company for a permit that would allow the field testing of genetically engineered wheat (*Triticum aestivum*) plants. The plants have been modified for expressing marker genes such as kanamycin resistance, herbicide tolerance, and anthocyanin production etc. The field test is proposed to start in December 1, 1994, on agricultural land in Yuma County, Arizona.

The Monsanto Agricultural Company application was submitted pursuant to the regulations found in 7 CFR Part 340, which regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products that are regulated articles. Under the regulations, an organism is considered a regulated article if it is genetically engineered (as defined in §340.1) from a donor organism, recipient organism, or vector or vector agent which is listed in §340.2 of the regulations, and the listed organism is a plant pest (as defined in §340.1). The regulations require that a person obtain a permit from the Animal and Plant Health Inspection Service (APHIS) prior to introducing a regulated article.

Pursuant to the procedures set forth in §340.3 of the regulations, we have prepared our preliminary findings in this letter for your review. This serves to give notice to the State and to provide the opportunity for the State to expressly indicate concurrence or nonconcurrence with our preliminary assessment. Please review the enclosed application documents and return acknowledgement, associated comments, and concurrence or reasons for nonconcurrence (if applicable) to APHIS within 30 days of receipt of this letter. Please use the enclosed form, and use additional sheets if needed for your response. It is very important that our office receive comments and opinions from State regulatory officials regarding the issuance of permits for the release of genetically engineered organisms into the environment.

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On the basis of our preliminary review of this application, we conclude that controlled field testing of the genetically engineered wheat plants described in this application will not present any risk of plant pest introduction or dissemination for the reasons cited below.

1. Environmental Impacts Related to the Recipient. The recipient organisms are wheat plants. Wheat is normally self-pollinated and pollen is viable for only 15 to 20 min, or up to 30 min under the best conditions. Thus, there is a lack of gene movement. To prevent any mechanical mixing, a minimum of 20 feet distance will be maintained between the transgenic and nontransgenic wheat plants.

2. Environmental Impacts Related to the Donor. The wheat plants for this field test have been altered via genetic engineering techniques to contain several different marker genes with different phenotypes, each plant carrying one or two such genes. The exact nature of some of these genes has been claimed as Confidential Business Information. One of these genes is neomycin phosphotransferase (*nptII*) that encodes resistance to the common antibiotic kanamycin.

Noncoding DNA regulatory sequences (promoters and terminators) were attached to the introduced genes to facilitate expression in plants. These regulatory sequences were derived from a plant pest, specifically cauliflower mosaic virus. None of the DNA regulatory sequences can cause plant disease by themselves or in conjunction with the genes that were introduced into the transgenic plants.

3. Environmental Impacts Related to the Vector and Vector Agent. The wheat plants in this experiment were transformed using the method of particle acceleration, also referred to as the biolistic or particle gun method of transformation. Plant tissues are bombarded with heavy particles, typically tungsten or gold, that are coated with DNA, with the result that particles are able to penetrate the barriers of the cell wall and the cell membrane and deliver the DNA to the interior of the cell. Research experience with transgenic plants produced by the particle acceleration method indicates that the engineered genes are typically integrated into the nuclear genome and segregate in a Mendelian fashion in subsequent generations. No plant pest risk associated with this method of transformation can be identified.

4. Quarantine of Organism and Final Disposition. The test site in Yuma County, Arizona, is expected to provide adequate physical security. Site monitoring and management practices that create a nonpropagative environment should provide the necessary degree of both biological and physical containment. At maturity, some seeds will be sent to Monsanto laboratories for further analysis. The remaining plant stubble and seeds will be mechanically incorporated into the

OR120018_BR_011670

soil. The containment measures described in the application should be sufficient to minimize any unplanned releases of the transgenic plant material.

Staff Contact

If you have any questions about this application or our preliminary findings, please contact Dr. Subhash Gupta, Biotechnologist, at Area Code (301) 436-8365 or facsimile number (301) 436-8669. Please refer to permit application number 94-024-01 in your correspondence regarding this application. APHIS hopes to maintain its excellent working relationship with your State and encourages your participation and comments prior to our final decision.

Sincerely,

/s/ SUBHASH GUPTA PH.D.

Sivramiah Shantharam, Ph.D.
Chief, Microorganisms Branch
Biotechnology Permits
Biotechnology, Biologics, and
Environmental Protection

2 Enclosures

cc:
R. Stoaks, PPQ, Sacramento, CA
S. Ingebritsen, BCTA, Hyattsville, MD
File 94-221-01

APHIS:BBEP:BP:SGUPTA:ajd:436-8365:8-30-94:9422101.stl

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ENVIRONMENTAL ASSESSMENT AND

FINDING OF NO SIGNIFICANT IMPACT

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture has prepared an environmental assessment in response to a permit application (APHIS Number 94-221-01) received from Monsanto Agricultural Company to conduct a field test with genetically engineered (transgenic) wheat (*Triticum aestivum*) plants. These transgenic wheat plants are regulated articles because they were developed with genetic material from known plant pests. The plants have been modified for expressing marker genes such as β-glucuronidase (*gus*), kanamycin resistance, glyphosate herbicide tolerance, and anthocyanin production. The identity of the glyphosate herbicide tolerance gene has been claimed as Confidential Business Information (CBI) by the applicant. The field test is scheduled to begin in December 1, 1994, on agricultural land in Yuma County, Arizona.

Although parts of the introduced gene constructs were derived from plant pathogens, the test should not pose a risk of the introduction or dissemination of a plant pest. We conclude that the field test will not present a significant impact, either individually or cumulatively, on the quality of the human environment; and have therefore, reached a finding of no significant impact on the environment.

(b) (6), (b) (7)(C)

John H. Payne
Acting Director
Biotechnology, Biologics, and Environmental Protection
Animal and Plant Health Inspection Service
United States Department of Agriculture
Date: OCT 21 1994

key words: Permit number 94-221-01; wheat (*Triticum aestivum*); glyphosate tolerance and kanamycin resistance marker genes

OR120018_BR_011672

I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA has prepared an environmental assessment in response to a permit application (APHIS Number 94-221-01) received from Monsanto Agricultural Company to field test genetically engineered wheat plants. These transgenic wheat plants are regulated articles because they were developed with genetic material from known plant pests. The plants have been modified for expressing marker genes such as β-glucuronidase (*gus*), kanamycin resistance, herbicide tolerance, and anthocyanin production. The identity of the herbicide tolerance gene has been claimed as CBI by the applicant. The field test is scheduled to begin in December 1, 1994, on agricultural land in Yellowstone County, Montana.

The wheat plants in this experiment were transformed using the method of particle acceleration also referred to as the biolistic or particle gun method of transformation. The selectable genetic marker genes aid in the selection of transformed plant tissues in the laboratory. Several of the noncoding DNA regulatory sequences i.e. sequences attached to the coding regions that control expression of the introduced coding sequences, were derived from bacterial and viral plant pathogens. The regulatory sequences cannot cause plant disease by themselves or in conjunction with the coding regions which they regulate in the constructs included in this field test. Once inserted into the chromosome of the recipient, the introduced genes are maintained and transmitted to other plants via pollen, in the same manner as any other genes.

The proposed field test is a controlled release of the regulated article into the environment. The transgenic wheat plants will be planted in plots that are separate from wheat plants not part of the experimental release. It is unlikely that any trait from the transgenic wheat will be transmitted to any other wheat or sexually compatible relative. Hence there will be no significant impact of the transgenic wheat plants in this field trial. This conclusion is based upon both the nature of the genetic modifications in these plants and the fact that genetic material from descendants of such crosses is unlikely to enter into wheat breeding stock or otherwise become established in the environment.

The APHIS review and analysis of the data indicate that the proposed field test should not present a risk of introduction and dissemination of a plant pest and should not have a significant impact, either individually or cumulatively, on the quality of the human environment.

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II. INTRODUCTION

A permit application was submitted to USDA-APHIS pursuant to regulations codified in 7 CFR Part 340 which are entitled "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests". The regulations govern the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products. Under § 340.0 of the regulations, a person is required to obtain a permit prior to introducing a regulated article. Prior to issuing a permit, APHIS prepares an analysis of the potential impacts associated with the proposed introduction, and publishes an environmental assessment which documents the analysis in accordance with regulations and guidelines implementing the National Environmental Policy Act (NEPA) of 1969 (42 USC 4321 *et seq.*); Regulations of the council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500-1508) ; USDA Regulations Implementing NEPA (7 CFR part 1b); APHIS Guidelines Implementing NEPA (44 FR 50381-50384; and 44 FR 51272-51274).

A genetically engineered organism is considered a regulated article if the donor organism, recipient organism, vector or vector agent used in engineering the organism belongs to one of the taxa listed in the regulation and is also a plant pest, or if there is reason to believe that it is a plant pest. The transgenic wheat plants described in this application are considered regulated articles because some of the introduced noncoding DNA regulatory sequences are derived from plant pests/pathogens.

III. ALTERNATIVES

APHIS has considered the following three alternative responses to the applicant's request for a permit to conduct the proposed field test: (1) deny the permit, (2) issue the permit for the test conditions proposed by the applicant, or (3) issue the permit with the stipulation of additional conditions for conduct of the field test. When APHIS issues field test permits, they typically include additional requirements such as filing field data reports. These field reports help APHIS evaluate the specific field test under permit, and they also provide guidance for evaluating future proposed field tests.

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IV. DESCRIPTION OF THE REGULATED ARTICLE

The transgenic wheat plants have been altered via genetic engineering techniques to contain several different marker genes with different phenotypes, each plant carrying one or two such genes. The exact nature of herbicide tolerant gene has been claimed as CBI. Although some of the genes were derived from natural plant pests, the genes themselves do not code for any trait conferring any plant pest or pathogen characteristic. The genetic marker gene, *nptII* aids in the selection of transformed plant tissues in the laboratory (Flavell et al., 1992; Jefferson et al., 1987). It is derived from *Escherichia coli* and encodes the enzyme neomycin phosphotransferase that confers resistance to the antibiotics neomycin and kanamycin. Another gene that is used as a marker gene is β-glucuronidase gene (*gus*) derived from the bacterium *E. coli*. This gene is also widely used in transgenic plants to facilitate the selection of transformed tissues in the laboratory (Jefferson et al., 1987).

All of the genetic constructs also include well-characterized noncoding DNA regulatory sequences derived from the plant pathogens cauliflower mosaic virus (CaMV). Plant pathogen derived noncoding DNA regulatory sequences include: the *35S* gene promoter from CaMV. None of the regulatory sequences introduced into the transgenic wheat lines can cause plant disease by themselves or in conjunction with the genes they regulate.

The transgenic wheat plants were produced using previously described protocols for transformation via particle acceleration that does not involve any live vector agent (Klein et al., 1992). Once inserted into the chromosome of the recipient, the introduced genes are maintained in the same manner as any other genes.

V. DESCRIPTION OF THE FIELD TEST

Field Experiments. The field test is scheduled to begin in June 1994. The test site will be located on agricultural land in Yuma County, Arizona. The objective of this field trial is to test the efficacy of various marker genes in wheat. Each test plot will consist of one to four rows, 4-12 inches apart and up to 20 feet long. The anticipated number of replications is from one to four. The transgenic material will cover less than 1.0 acre with no more than 500,000 plants. To prevent any mechanical mixing, a minimum of 20 feet distance will be maintained between the transgenic and nontransgenic wheat plants. The 20 foot strip may be either mowed, uncropped, or planted to a crop other than wheat.

Containment of genetic material. Dissemination of genetic material from the genetically engineered wheat plants is unlikely. Wheat is normally self-pollinated and pollen is viable for only 15 to 20 min, or up to 30 min under the best conditions. Thus, there is a lack of gene movement. To prevent any mechanical mixing, a minimum of 20 feet

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distance will be maintained between the transgenic and nontransgenic wheat plants.

Field Observation, Monitoring, and Final Disposition of Test Plants. The field test plots will be monitored on a regular basis during the course of the growing season to evaluate agronomic characteristics. As much as possible, normal agricultural practices will be used for the plants grown in the test plots. The wheat will be harvested by hand or with a field plot harvester. If a machine is used, it will be thoroughly cleaned to exiting the plot area. Some seed will be sent to Monsanto laboratories in Chesterfield, MO for further analysis. All residual plant material will be mechanically incorporated into the soil. The site will be monitored following the growing season and any emerging volunteer germinating wheat will be destroyed.

VI. POTENTIAL ENVIRONMENTAL IMPACT

The transgenic wheat plants have been modified by the integration of one of several marker genes including herbicide tolerance to glyphosate. These plants also contain a gene that confers resistance to kanamycin. Other than these modification, the transgenic wheat lines should share the characteristics of the parental, nontransformed wheat cultivars. These modifications are not expected to alter significantly the production of any toxic or deleterious constituents as compared to nontransformed wheat plants. Various safeguard issues as discussed below, concerning transgenic wheat were considered at the workshop convened by The Keystone Center, Colorado (Qualset, 1990).

Potential for Persistence of the Modified Plants in the Environment. The proposed field test is a controlled release of the regulated article into the environment. The wheat plants will be grown under standard agricultural conditions in the field and will be planted in a separate plot from those which are not part of the planned introduction. The test site will be physically separated from other plants, and the plants within the test site will be destroyed at the conclusion of the growing season. The field will be cultivated or plowed as needed to destroy any wheat plants remaining in the field. Volunteer wheat seedlings found during monitoring the following year will be destroyed.

Increased weediness. Wheat is not a weed, and the genetic modifications should not significantly influence the ability of the plants to persist in the environment. Wheat does not reproduce vegetatively when grown in the field, so the only way for the regulated article to persist beyond the growing season is by the production of seeds via sexual reproduction. Jointed goatgrass (*Aegilops cylindricum*) is a major weed problem in the cereal producing areas of the western United States (Donald and Ogg, 1991). There is a risk of transfer of an introduced gene from wheat to jointed goatgrass. However, the likeliness of increasing weediness of non-target organisms is not there because the weed control will follow

OR120018_BR_011676

acceptable practices for wheat by using labelled herbicides and or hand weeding. There are also adequate physical, and biological safety features built into the field that will minimize the chances of outcrossing (see V).

Potential for and Impact of Gene Transfer to Other Plants. It is unlikely that the introduced genes will move inadvertently from the transgenic test plants and persist in the genome of progeny. Like most cultivated varieties of wheat, the transformed cultivars of wheat is self-pollinated and pollen is viable for only 15 to 20 min, or up to 30 min under the best conditions. Therefore, it is unlikely that the introduced genes will be transmitted from the field test plants and become established in the environment.

Impact on Existing Agricultural Uses. The wheat plants have been genetically modified by the integration of one of several marker genes including herbicide tolerance to glyphosate. The objective of this field trial is to test the efficacy of various marker genes in transgenic wheat plants. The use of these plants in the proposed field trial should not affect current agricultural practices with wheat.

Impact on Nontarget Organisms. The genes introduced into the transgenic wheat lines are designed to determine the efficacy of marker genes. They should not increase the likelihood that the plants will produce constituents with toxic or deleterious effects on any nontarget floral or faunal species besides the intended target plants. Any such unexpected effects would be minimal by virtue of being confined to the area within the field plot. Since there is no identifiable direct effect of this field test on any wild plant species, there is no apparent risk to any threatened or endangered plant species.

Cumulative Environmental Effects: The transgenic wheat will not be allowed to persist at the test site beyond the effective termination of the test. Also, physical, biological, and temporal safety features built into the test effectively prevent any potential gene escape from these plants into nontarget organisms. Therefore, there is very little chance for cumulative impacts as a result of introducing genetically modified wheat plants into the environment.

Alteration in Susceptibility to Plant Pathogens. There is no indication that the transgenic wheat plants will be substantially altered in their susceptibility to challenge by pathogens or insects. If there were any unanticipated changes in disease susceptibility, the effects would be confined to these plants and the test plot. The plants in the experimental plot will be monitored for a wide range of agronomic traits, including any abnormal insect populations or unexpected plant diseases. Approved pesticides may be applied, if necessary, in accordance with accepted practices of wheat cultivation.

OR120018_BR_011677

Impact on Human Health. The applicant recognizes that any food and feed uses of the transgenic wheat must be in compliance with the guidelines published in the Federal Register by the United States Food and Drug Administration (57 FR 22984, May 29, 1992).

VII. CONCLUSIONS

The APHIS review and analysis of the data indicate that the proposed field test should not present a risk of introduction and dissemination of a plant pest and should not have a significant impact either individually or cumulatively, on the quality of the human environment. APHIS' conclusion is based on the following:

1. Wheat plants were transformed using the method of particle acceleration also referred to as the biolistic or particle gun method of transformation. The only significant means by which the introduced genes can be transmitted to other organisms is by sexual recombination with sexually compatible plants.

2. Although parts of the gene constructs introduced into the transgenic wheat are derived from plant pathogens, the transgenic plants are not diseased nor do they present any identifiable risk of disease to other plants.

3. Dissemination of genetic material from the genetically engineered wheat plants is unlikely. Wheat is normally self-pollinated and pollen is viable for only 15 to 20 min, or up to 30 min under the best conditions.

4. Site monitoring and management practices that create a nonpropagative environment should provide the necessary degree of both biological and physical containment.

APHIS concludes that the proper alternative is to issue the permit with supplemental permit conditions (see Appendix A). These conditions include a requirement for a data report which will aid APHIS in the evaluation of the specific field test under permit and will provide guidance for evaluating future proposed field tests.

OR120018_BR_011678

VIII. LITERATURE CITED

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Flavell, R. B., Dart, E., Fuchs, R. L., and Fraley, R. T. 1992. Selectable marker genes: safe for plants? Bio/Technology 10:141-144.

Qualset, C. 1990. Wheat. In: Workshop on safeguards for planned introduction of transgenic corn and wheat (Eds. Giddings, L. V., Dilley, A. P., Starke, L.), pp. 3-13.

Jefferson, R. A., Kavanagh, T. A., Bevan, M. W. 1987. GUS fusions: beta-glucuronidase as a sensitive and versatile gene fusion marker in higher plants. EMBO Journal 6:3901-3907.

Klein, T. M., Arentzen, R., Lewis, P. A. Fitzpatrick-McElligott, S. 1992. Transformation of microbes, plants, and animals by particle bombardment. Bio/Technology 10:286-291.

OR120018_BR_011679

IX. PREPARERS AND REVIEWERS

Biotechnology, Biologics, and Environmental Protection

Biotechnology Permits

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Hyattsville, MD 20782

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OR120018_BR_011680

APPENDIX A - Permit with Standard and Supplemental Conditions

1. Permit: APHIS Form 2000 (2 pages)
2. Standard Permit Conditions
3. Supplemental Permit Conditions

OR120018_BR_011681

Supplemental Permit Conditions

Permit Number 94-221-01

1. Biotechnology, Biologics, and Environmental Protection (BBEP) or a Regional Biotechnologist will conduct an inspection of the test site at the beginning of the test. The permittee is required to notify the State regulatory official, and the appropriate Regional Biotechnologist (see attached map) at least 1-week before the test begins.

2. Additional inspections may be conducted by the Regional Biotechnologist. The permittee is required to notify the Regional Biotechnologist at least 1-week before termination of the experiment.

3. **A field test data report must be submitted within 12 months after the permit issuance date. If a field test is still in progress at 12 months or any multiple of 12 months after the permit issuance date, additional field test data reports must be submitted to APHIS within subsequent 12 month periods. Final reports for those field tests lasting more than 12 months must be submitted to APHIS 6 months after the termination of the field test.** Field test reports shall include: methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment. We encourage the inclusion of other types of data if the applicant anticipates submission of a petition for determination of regulatory status for their regulated article. APHIS views these data reports as critical to our assessment of plant pest risk and development of regulatory policies based on the best scientific evidence. Failure by an applicant to provide data reports in a timely manner for a field trial may result in the withholding of permission by APHIS for future field trials.

Confidential Business Information (CBI) will be handled according to the APHIS policy statement at 50 FR 38561-63.

4. The test site shall be monitored for any volunteer plants after the completion of the test until the end of the following growing season for wheat in the area.

5. BBEP should be notified of any proposed changes to the protocol given in the permit application.

6. This approved Biotechnology Permit (APHIS form #2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (1) for the use of any non-genetically engineered plant pest or pathogens as challenge inoculum; (2) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (3) experimental use of unregistered chemical; and (4) food or feed use of genetically engineered crops harvested from the field experiment.

OR120018_BR_011682

94-221-01

Response to the FAX from Ralph Stoaks 11/1/94

FAX Transmittal Sheet



Biotechnology Permits

Biotechnology, Biologics, and Environmental Protection
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
6505 Belcrest Road, FB-845
Hyattsville, MD 20782

DATE: November 1, 1994 Number of pages, including coversheet: 2

TO: Dr. Ralph Stoaks, Regional Biotechnologist

FAX: (916) 551-3046

FROM: Subhash C. Gupta, Ph.D. (b) (6), (b) (7)(C) 11/1/94

FAX: (301) 436-8669 Tel: (301) 436-8365

PERMIT: 94-221-01, Page 1 of EA

I thank you very much for bringing to my attention the error in the EA of permit application 94-221-01. I have corrected this mistake on page one and am sending the corrected page to all concerned parties.

Once again, I thank you for sending the fax. If there are more questions please contact me at (301) 436-8365.

OR120018_BR_011683

FAX Transmittal Sheet

Biotechnology Permits
Biotechnology, Biologics, and Environmental Protection
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
6505 Belcrest Road, FB-845
Hyattsville, MD 20782

DATE: November 1, 1994 Number of pages, including coversheet: 2

TO: Dr. Kent Croon, Regulatory Affairs, Monsanto Agricultural Co.

FAX: (314) 537-7085 TEL: (314) 537-7488

FROM: Subhash C. Gupta, Ph.D. (b) (6), (b) (7)(C) 11/1/94

FAX: (301) 436-8669 TEL: (301) 436-8365

PERMIT: 94-221-01, Page 1 of EA

We have noticed an error on page one of the EA for permit application 94-221-01. I have corrected this error and am sending the corrected page to you for replacement in the original EA--94-221-01.

If there are any questions regarding this fax, please contact me at (301) 436-8365.

OR120018_BR_011684

FAX Transmittal Sheet

Biotechnology Permits
Biotechnology, Biologics, and Environmental Protection
Animal and Plant Health Inspection Service
U.S. Department of Agriculture
6505 Belcrest Road, FB-845
Hyattsville, MD 20782

DATE: November 1, 1994 Number of pages, including coversheet: 2

TO: Glen Thaxton, Assistant Director

FAX: (602) 407-2959 TEL: (602) 407-2952

FROM: Subhash C. Gupta, Ph.D. (b) (6), (b) (7)(C) 11/1/94

FAX: (301) 436-8669 TEL: (301) 436-8365

PERMIT: 94-221-01, Page 1 of EA

It was brought to my attention that I have made an error on page one of the EA for permit application 94-221-01. I have corrected this mistake and am sending the corrected page to all concerned parties for replacement in the original EA--94-221-01.

If there are any questions regarding this fax, please contact me at (301) 436-8365.

OR120018_BR_011685

2I. SUMMARY

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA has prepared an environmental assessment in response to a permit application (APHIS Number 94-221-01) received from Monsanto Agricultural Company to field test genetically engineered wheat plants. These transgenic wheat plants are regulated articles because they were developed with genetic material from known plant pests. The plants have been modified for expressing marker genes such as β-glucuronidase (*gus*), kanamycin resistance, herbicide tolerance, and anthocyanin production. The identity of the herbicide tolerance gene has been claimed as CBI by the applicant. The field test is scheduled to begin in December 1, 1994, on agricultural land in Yuma County, Arizona.

The wheat plants in this experiment were transformed using the method of particle acceleration also referred to as the biolistic or particle gun method of transformation. The selectable genetic marker genes aid in the selection of transformed plant tissues in the laboratory. Several of the noncoding DNA regulatory sequences i.e. sequences attached to the coding regions that control expression of the introduced coding sequences, were derived from bacterial and viral plant pathogens. The regulatory sequences cannot cause plant disease by themselves or in conjunction with the coding regions which they regulate in the constructs included in this field test. Once inserted into the chromosome of the recipient, the introduced genes are maintained and transmitted to other plants via pollen, in the same manner as any other genes.

The proposed field test is a controlled release of the regulated article into the environment. The transgenic wheat plants will be planted in plots that are separate from wheat plants not part of the experimental release. It is unlikely that any trait from the transgenic wheat will be transmitted to any other wheat or sexually compatible relative. Hence there will be no significant impact of the transgenic wheat plants in this field trial. This conclusion is based upon both the nature of the genetic modifications in these plants and the fact that genetic material from descendants of such crosses is unlikely to enter into wheat breeding stock or otherwise become established in the environment.

The APHIS review and analysis of the data indicate that the proposed field test should not present a risk of introduction and dissemination of a plant pest and should not have a significant impact, either individually or cumulatively, on the quality of the human environment.

OR120018_BR_011686

FILE COPY

OCT 2 7 1994

(b) (6), (b) (7)(C)
Monsanto Agricultural Company BB3A
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Subject: Biotechnology Permit Number 94-221-01 to Conduct a Planned Release of Genetically Engineered Wheat Plants.

The above permit has been approved after a Finding of No Significant Impact (FONSI) and a finding that the genetically engineered organisms do not present a risk of plant pest introduction or dissemination. A copy of the environmental assessment is enclosed. You must adhere to the standard and supplemental conditions enclosed.

This permit should not be taken as any type of efficacy determination of the genetically engineered organisms.

Sincerely,

Arnold S. Foudin, Ph.D.
Deputy Director
Biotechnology Permits

Enclosure:

Permit 94-221-01
EA 94-221-01
Supplemental Permit Conditions
Standard Permit Conditions
Map - Regional Biotechnologists

cc:
G. Thaxton, Asst. Director, AZ Dept. of Agric., P.O. Box 234, Phoenix, AZ 85001
R. Stoaks, PPQ, Sacramento, CA
S. Ingebritsen, BCTA, Hyattsville, MD
File 94-221-01

APHIS:BBEP:BP:SGUPTA:RAS:436-7612:10/26/94:94-221-01.LTR

OR120018_BR_011687

Reassigned to NRC

1/11/95 3:38 pm Release Tracking Sheet

FILE COPY

Bp number: 95-010-02r

Intro type: Release Renewal Permit:
Received: 1/10/95 Clock stop: Clock start: Due: 5/10/95
Institution: Monsanto
Resp person: (b) (6), (b) (7)(C)
Recipient: Wheat
Status: Pending Sites: 2 Acre: 2.40
Reviewer: MB SMK
CBI status: CBI
Phenotype: MG ~~and/or Herbicide Tolerant~~
Comments:
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 314-537-7085

		Initial	Date
1.	[✓] Assign Bp number and initial data entry	[CM]	[1/10/95]
2.	[ ] Letter of notification to Applicant	[ ]	[ ]
3.	[✓] File and this tracking sheet to reviewer	[CM]	[1/11/95]
4.	[✓] Letter of preliminary assessment to State	[ ]	[3/7/95]
5.	[✓] Reviewer checks data entries and returns this sheet to permit unit	[SMK]	[1/23/95]
6.	[✓] State response listed by State/Region/Sites		
	IL NER 1 State Response	[CM]	[3/28/95]
	MT WR 1 State Response	[CM]	[4/4/95]
7.	[ ] Permit issued or denied	[ ]	[ ]
8.	[ ] Enter final data into database	[ ]	[ ]

OR120018_BR_011688

1/11/95 3:37 pm

Release Gene Data Entry Tracking Sheet

FILE COPY

CURRENT IN DATABASE

Bp number: 95-010-02r	Intro type: Release	Renewal Permit:		Received:	1/10/95
Clock stop:	Clock start:	Due: 5/10/95		Issue/deny:	
Institution: Monsanto		Resp person: (b) (6), (b) (7)(C)			
Recipient: Wheat					
Status: Pending	Sites: 2	Acre: 2.40	Reviewer: ~~MB~~ SMK	CBI status: CBI	
Location: IL MT					
Comments:					

Category: 1) MG ~~2) MG~~	2) MG	3) MG
Phenotype: Kanamycin resistant ~~and/or~~	glyphosate tolerant	~~and/or~~ CBI

SM?:	Gene:	Donor:
SM		

Done?

Reviewer of this sheet: DH JW KR SG SK SS VM

(b) (4)

Notice

Confidential Business Information

Some information in the attached material may be entitled to treatment as trade secret or proprietary data under Section(b)(4) of the Freedom of Information Act (FOIA) [5 U.S.C. 552(b)(4)].

Any person handling or using the attached data in any way is responsible for preventing unauthorized disclosure during possession.

Maintain this document under secure conditions.

Return to the Document Control Officer after use.

This application deals with:

MONSANTO — wheat — MON
States: IL, MT

Identification Number:

95-010-02

The attached information is not to be published, reproduced, publicly discussed, included in response to a FOIA request, or otherwise released without the explicit written authorization of the appropriate division director or designee.

Please disqualify yourself if there is any potential Conflict of Interest

OR120018_BR_011690

This application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq. and the Plant Quarantine Act (7 U.S.C. 151 et seq.)). The information will be used to determine eligibility to receive all types of permits. No permit shall be issued until this application has been approved.

CONTAINS C B I

See reverse side for additional information

FORM APPROVED OMB NO. 0579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

(Genetically Engineered Organisms or Products)

94-247PR
95-010-02

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

1. NAME AND ADDRESS OF APPLICANT

(b) (6), (b) (7)(C)

Monsanto Company
700 Chesterfield Parkway North, St. Louis, MO 63198
Area Code (314) 537-7488

2. PERMIT REQUESTED ("X" one)

- [ ] Limited - Interstate Movement
- [ ] Limited - Importation
- [X] Release into the Environment
- [ ] Courtesy Permit

3. THIS REQUEST IS *("X" one)*

- [X] New
- [ ] Renewal
- [ ] Supplemental

4. TELEPHONE NUMBER

(b) (6), (b) (7)(C)

5. MEANS OF MOVEMENT

- [X] Mail
- [ ] Baggage or Handcarried
- [X] Common Carrier
- By whom _____

6. GIVE THE FOLLOWING *(if applicable) (if more space is needed, attach additional sheet)*

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism:	See Attached			
b. Recipient Organism:				
c. Vector or Vector Agent:				
d. Regulated Organism or Product:				
e. If product, list names of constituents:				

7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS

See Attached

8. DATE *(or inclusive dates of period)* **OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE**

April 1, 1995 - December 31, 1995

9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

See Attached

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

See Attached

11. ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* **ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT**

None

12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

N/A

13. SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON	15. PRINTED NAME AND TITLE	16. DATE
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	1/9/95

FOR APHIS USE ONLY

State Notification Sent	State Review Received	Permit Issued
03-07-95	IL 3-28-95 MT 4-3-95	[X] Yes [ ] No

Date of Determination	Permit No.	No. of Permit Labels Issued	Supplemental Conditions Enclosed
	95-010-02	N/A	[X] Yes [ ] No

Signature of BBEP Official	Date	Expiration Date
Arnold Foudin, Deputy Director	04-17-95	04-17-96

OR120018_BR_011691

CONTAINS C B I

	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article	X	
b	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics)	X	
c	A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article	X	
d	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced	X	
e	A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design	X	
f.	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: donor organism, recipient organism; vector or vector agent; constituent of each regulated article which is a product, and, regulated article.	X	
g	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location, field trial location, pilot project location, production, propagation, and manufacture location, proposed sale and distribution location)	X	
h	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.	X	
i	A detailed description of the proposed method of final disposition of the regulated article	X	

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

OR120018_BR_011692

CONTAINS C B I
95-010-02

INFORMATION SUBMITTED TO THE UNITED STATES DEPARTMENT OF AGRICULTURE IN SUPPORT OF AN APPLICATION TO FIELD TEST

TESTING OF MARKER GENES IN GENETICALLY ENGINEERED WHEAT PLANTS

94-247PR

January 9, 1994

Volume 1 of 1

Report Compiled by:
(b) (6), (b) (7)(C)

Confidential Business Information Deleted

MONSANTO AGRICULTURAL COMPANY
700 Chesterfield Parkway North • St. Louis • Missouri • 63198

OR120018_BR_011693

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (IOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (IOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

OR120018_BR_011694

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.[1]

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of marker genes in plants and their use in insect and virus resistant and herbicide tolerant crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

1 In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011695

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Calgene, Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

OR120018_BR_011696

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for wheat has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

OR120018_BR_011697

ATTACHMENT
CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION
MARKER GENES IN WHEAT

Page	Category of Information	Justification
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011698

3	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011699

8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
13	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
14	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
14	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
14	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011700

15	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
15	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
16	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
17	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
17	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
17	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
18	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
19	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
19	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
20	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
21	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011701

21	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
21	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
22	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
23	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
23	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
24	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
25	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
25	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
26	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
26	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
27	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011702

27	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
28	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
29	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
29	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
30	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011703

CONTAINS C B I

DISTRIBUTION

	CBI	CBI Deleted
USDA	1 Copy	1 Copy
State of Montana	-	1 Copy
State of Illinois	-	1 Copy
(b) (6), (b) (7)(C) [redacted]	1 Copy	-
	1 Copy	-
REGISTRATION FILES	1 Copy	1 Copy

OR120018_BR_011704

CONTAINS C B I

TABLE OF CONTENTS

	page
VOLUME 1	
APHIS FORM 2000	
APHIS FORM 2000 ATTACHMENTS	1

OR120018_BR_011705

CONTAINS C B I

APHIS FORM 2000 ATTACHMENTS

This request for a Release into the Environment Permit is to allow the field testing of marker genes in genetically modified wheat at the locations specified in item 10. All of the information required to support this application is found in this volume.

The vector constructs that may be a part of this field experiment are:

PV-TXSM08, PV-TXSM09, PV-TXCT16, PV-TXCT17, PV-TXCT18, PV-TXSM10, PV-TXCT19, PV-TXCT20, PV-TXCT21, PV-TXCT22, PV-TXCT23, PV-TXCT24, PV-TXCT25, and PV-TXCT26.

Item 6. The following is the information required to identify the donor, recipient, and regulated organisms and vector agent:

a) For Event PV-TXSM08:

		Scientific Name	Common Name
CBI CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

b) For Event PV-TXSM09:

		Scientific Name	Common Name
CBI CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

c) For Cotransformation Event PV-TXCT16:

Plasmid vector PV-TXSM09:

See description above.

OR120018_BR_011706

Plasmid vector PV-TXSM06:

		Scientific Name	Common Name
CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

d) For Cotransformation Event PV-TXCT17:

Plasmid vector PV-TXSM09:

See description above.

Plasmid vector PV-TXSM01:

		Scientific Name	Common Name
CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

e) For Cotransformation Event PV-TXCT18:

Plasmid vector PV-TXSM08:

See description above.

Plasmid vector PV-TXSM06:

See description above.

OR120018_BR_011707

f) For Event PV-TXSM10:

		Scientific Name	Common Name
CBI CBI	a. Donor Organism	[redacted] (b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

g) For Cotransformation Event PV-TXCT19:

Plasmid vector PV-TXSM10:

See description above.

Plasmid vector PV-TXSM06:

See description above.

h) For Cotransformation Event PV-TXCT20:

Plasmid vector PV-TXSM11:

		Scientific Name	Common Name
CBI CBI	a. Donor Organism	[redacted] (b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM06:

See description above.

CONTAINS C B I

i) **For Cotransformation Event PV-TXCT21:**

Plasmid vector PV-TXSM11:

See description above.

Plasmid vector PV-TXSM09:

See description above.

j) **For Cotransformation Event PV-TXCT22:**

Plasmid vector PV-TXSM12:

		Scientific Name	Common Name
CBI CBI	a. Donor Organism	[redacted] (b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM06:

See description above.

k) **For Cotransformation Event PV-TXCT23:**

Plasmid vector PV-TXSM12:

See description above.

Plasmid vector PV-TXSM09:

See description above.

OR120018_BR_011709

l) For Cotransformation Event PV-TXCT24:

Plasmid vector PV-TXSM12:

See description above.

Plasmid vector PV-TXSM07:

		Scientific Name	Common Name
CBI CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

m) For Cotransformation Event PV-TXCT25:

Plasmid vector PV-TXSM11:

See description above.

Plasmid vector PV-TXSM04:

	Scientific Name	Common Name
a. Donor Organism	Tn5	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

n) For Cotransformation Event PV-TXCT26:

Plasmid vector PV-TXSM12:

See description above.

Plasmid vector PV-TXSM04:

See description above.

CONSTRUCT DESCRIPTION FOR PV-TXSM08

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMP1/**[redacted] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [redacted]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.

CBI [redacted]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[redacted] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [redacted]

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants

CBI [redacted]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011712

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT16

PV-TXSM09 AND PV-TXSM06 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[redacted] A caulimovirus promoter plus intron.

See description above.

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011713

CONSTRUCT DESCRIPTION FOR PV-TXCT16 (continued)

CONSTRUCT DESCRIPTION FOR PV-TXSM06

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CBI **CMoVa/(b) (4)** A caulimovirus promoter plus intron.

See description above.

Herbicide Tolerance Marker Gene 1 Expression of this gene in plant cells serves as a selectable marker for transformation.

CBI [redacted]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011714

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT17

PV-TXSM09 AND PV-TXSM01 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[(b) (4)] A caulimovirus promoter plus intron.

See description above.

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

OR120018_BR_011715

CONSTRUCT DESCRIPTION FOR PV-TXCT17 (continued)

CONSTRUCT DESCRIPTION FOR PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[redacted] A caulimovirus promoter plus intron.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

CBI [redacted]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011716

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT18

PV-TXSM08 AND PV-TXSM06 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM08

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMP1/**[redacted] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

See description above.

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011717

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXSM06

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CBI **CMoVa** (b) (4) A caulimovirus promoter plus intron.

See description above.

Herbicide Tolerance Marker Gene 1 Expression of this gene in plant cells serves as a selectable marker for transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011718

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXSM10

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[(b) (4)] A caulimovirus promoter plus intron.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CBI **CMoVa/**[(b) (4)] A caulimovirus promoter plus intron.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.

CBI [(b) (4)]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

(14)

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT19

PV-TXSM10 AND PV-TXSM06 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM10

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[(b) (4)] A caulimovirus promoter plus intron.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CBI **CMoVa**[(b) (4)] A caulimovirus promoter plus intron.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011720

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXSM06

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[(b) (4)] A caulimovirus promoter plus intron.

See description above.

Herbicide Tolerance Marker Gene 1 Expression of this gene in plant cells serves as a selectable marker for transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011721

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT20

PV-TXSM11 AND PV-TXSM06 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM11

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **TSP2/**(b) (4) The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.

CBI [redacted]

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CBI **TSP2/**(b) (4) The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011722

CONSTRUCT DESCRIPTION FOR PV-TXCT20 (continued)

CONSTRUCT DESCRIPTION FOR PV-TXSM06

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[redacted] A caulimovirus promoter plus intron.

See description above.

Herbicide Tolerance Marker Gene 1 Expression of this gene in plant cells serves as a selectable marker for transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011723

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT21

PV-TXSM11 AND PV-TXSM09 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM11

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **TSP2/**(b) (4) The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CBI **TSP2/**(b) (4) The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011724

CONSTRUCT DESCRIPTION FOR PV-TXCT21 (continued)

CONSTRUCT DESCRIPTION FOR PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[(b) (4)] A caulimovirus promoter plus intron.

See description above.

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT22

PV-TXSM12 AND PV-TXSM06 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM12

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **TSP3/**(b) (4) The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

CBI [redacted]

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CBI **TSP3/**(b) (4) The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011726

CONSTRUCT DESCRIPTION FOR PV-TXCT22 (continued)

CONSTRUCT DESCRIPTION FOR PV-TXSM06

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**(b) (4) A caulimovirus promoter plus intron.

See description above.

Herbicide Tolerance Marker Gene 1 Expression of this gene in plant cells serves as a selectable marker for transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011727

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT23

PV-TXSM12 AND PV-TXSM09 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM12

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **TSP3/**(b) (4) The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CBI **TSP3/**(b) (4) The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011728

CONSTRUCT DESCRIPTION FOR PV-TXCT23 (continued)

CONSTRUCT DESCRIPTION FOR PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[(b) (4)] A caulimovirus promoter plus intron.

See description above.

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011729

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT24

PV-TXSM12 AND PV-TXSM07 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM12

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **TSP3/**(b) (4) The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CBI **TSP3/**(b) (4) The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011730

CONSTRUCT DESCRIPTION FOR PV-TXCT24 (continued)

CONSTRUCT DESCRIPTION FOR PV-TXSM07

This construct is a free delivery: pUC-Kan vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[(b) (4)] A caulimovirus promoter plus intron.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CBI **CMoVa/**[(b) (4)] A caulimovirus promoter plus intron.

See description above.

Herbicide Tolerance Marker Gene 1 Expression of this gene in plant cells serves as a selectable marker for transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011731

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT25

PV-TXSM11 AND PV-TXSM04 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM11

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **TSP2/**(b) (4) The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CBI **TSP2/**(b) (4) The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011732

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[redacted]A caulimovirus promoter plus intron.

See description above.

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011733

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXCT26

PV-TXSM12 AND PV-TXSM04 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM12

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **TSP3/**(b) (4) The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CBI **TSP3**(b) (4) The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011734

CONTAINS C B I

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[(b) (4)] A caulimovirus promoter plus intron.

See description above.

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011735

Item 9: The donor, recipient and vector organisms were collected in the United States. The vector construct and transgenic wheat were developed by Monsanto at the Chesterfield Village Laboratories. The planting material will be wheat seeds produced by and shipped from:

(b) (6), (b) (7)(C)
The Agricultural Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
Tel.: (b) (6), (b) (7)(C)
Fax: 314-537-6950

Item 10. The locations of the field experiment is as follows (2):

(b) (6), (b) (7)(C), (b) (4) **Illinois**
Jersey County

Principle Investigator: (b) (6), (b) (7)(C)
The Agricultural Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
Tel.: (b) (6), (b) (7)(C)
Fax: 314-537-6950

(b) (6), (b) (7)(C), (b) (4) **Montana**
Yellowstone County

Principle Investigator: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) MT (b) (6), (b) (7)(C), (b) (4)
tel: (b) (6), (b) (7)(C), (b) (4)

Item 13a. The transgenic wheat which is the subject of this permit request, was developed by scientists at Monsanto. For additional information contact the applicant of this permit.

Item 13b. The transgenic material that is the recipient of the added genes is the CIMMYT(Centro Internaclonal de Mejoramiento de Maiz y Trigo, Facimile 52-595-41069) line Bobwhite. The line Bobwhite was designated to a group of advanced lines derived from the cross Aurora/Kalyan/Bluebird/3/Woodpecker CM33203. This cross was made at CIMMYT in 1973.

Bobwhite is in general semidwarf, carries resistance to septoria tritici, leaf rust, and the gene YR9 for stripe rust. The Bobwhite lines carry the 1B/1R translocation i.e. 1BS is translocated by 1RS of rye. The 1B/1R was derived from the variety Aurora from the USSR. Despite the fact that it carries 1B/1R translocation associated with poor quality(stickiness), industrial quality of Bobwhite is good, and acceptable in most countries.

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The Bobwhite line has been genetically -modified by particle bombardment for co-transformation of one of the scorable or selectable markers described . At present no molecular or segregation data is available from the lines that will be evaluated in the field trial. However the original transformed plants have been qualitatively evaluated for gene expression of the selectable marker/s with positive results.

Item 13c. The description of the plasmid vector as inserted into these wheat plants is as follows:

VECTOR DESCRIPTION FOR FREE DELIVERY

Free delivery vectors are engineered to contain multiple chimeric plant expression genes in either the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11) or pMON 10081, a derivative of the high copy *E. coli* plasmid pUC119. These vectors contain either the B-lactamase gene conferring bacterial ampicillin resistance (pUC119) or the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance (pMON 10081). The antibiotic markers are driven by bacterial promoters which do not contain the regulatory elements necessary to express in plants. They are also used to propagate the plasmid in *E. coli* in order to produce sufficient DNA quantities for transformation experiments (further described in Delivery System Description).

FREE DELIVERY PARTICLE GUN (MONSANTO)

Introduction of DNA into plant tissue with the "biolistic" particle bombardment method has been described in detail by Klein et al. (1987, Nature 327: 70-73; 1988a, Bio/Technology 6: 559-563; and 1988b, Proc Natl Acad Sci USA 85: 4305-4309). The transgenic material in this application was produced using the commercially available particle delivery systems. Detailed instructions are available from the manufacturers. Briefly, DNA is precipitated onto microscopic (~1 μ diameter) tungsten or gold particles using calcium chloride and spermidine. A drop (2.5μl) of the coated particles is accelerated at a high velocity allowing the particles to penetrate the target plant cells, where the DNA is deposited and incorporated into the plant cell genome. The cells are incubated on a tissue culture medium which supports the growth of embryogenic callus. The introduced DNA contains a gene(s) encoding for resistance to either antibiotics (e.g., the NPTII gene for resistance to kanamycin and G418) or genes conferring herbicide resistance. The plant cells are grown in the presence of an appropriate antibiotic or herbicide, and only the transformed cells continue to grow. Plants are regenerated from the resistant embryogenic callus tissue, and are assayed for the presence of the introduced gene(s). The free delivery vectors are engineered to contain multiple chimeric plant expression genes in high copy E. coli plasmids.

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CONTAINS C B I

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Amp

The free delivery vectors are engineered to contain multiple chimeric plant expression genes in the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). The pUC119 plasmid contains the ß-lactamase gene conferring bacterial ampicillin resistance. Several chimeric plant expression genes can be introduced into pUC119. These include the marker genes required for selection of the transformed plant tissue, and one or more genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Kan

The free delivery vectors contain multiple chimeric plant expression genes engineered into pMON10081. The pMON10081 plasmid is a derivative of the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). It was constructed by fusing the 1.3 Kb FspI-DraI origin of replication fragment from pUC119, to the 1.3 Kb SmaI-HindIII (Klenow filled) fragment from pKC7 (Rao and Rogers 1979, Gene 7: 79). The pKC7 fragment contains the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance. The ß-lactamase gene conferring bacterial ampicillin resistance was completely deleted. Several chimeric plant expression genes can be introduced into pMON10081. These include the marker genes required for selection of the transformed plant tissue, and one or more chimeric genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

Item 13d. The plasmid vectors were constructed at the research laboratories of Monsanto Co. in St. Louis, Missouri. The initial wheat plants transformed with these vectors were also developed at the research laboratories of Monsanto Co. in St. Louis, Missouri, USA.

Item 13e. The information regarding the description of the propose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design is found in the protocol on the following page.

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CONTAINS C B I

PROPOSED EXPERIMENTAL PROGRAM

MARKER GENES IN GENETICALLY MODIFIED WHEAT

Purpose of the test:

To test the efficacy of various marker genes in wheat.

Investigators:

* Principal Monsanto investigator at St. Louis, MO and for Jerseyville, Illinois field site:

(b) (6), (b) (7)(C)
The Agriculture Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
phone: (b) (6), (b) (7)(C)
FAX: (314) 537-6950

* Principal investigator at Billings, Montana field site:

(b) (6), (b) (7)(C), (b) (4)
MT
phone: (b) (6), (b) (7)(C), (b) (4)

Field Test Design:

* The test will use an experimental design that best addresses the test objectives while dealing with limited seed quantities.

* Treatments will be chosen from the following:

    * Chemical herbicide: Use of commercially available herbicides or proprietary chemistry to evaluate the effects of application on weed control and crop tolerance.

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* Timing of application: Chosen from growth stages between emergence through first flowering including sequential applications at two or more growth stages.

* Type of application: Over-the-top or post-directed.

Genotypes:

* Homozygous and segregating progeny of lines transformed with one of the following vectors:

  PV-TXSM08, PV-TXSM09, PV-TXCT16, PV-TXCT17, PV-TXCT18, PV-TXSM10, PV-TXCT19, PV-TXCT20, PV-TXCT21, PV-TXCT22, PV-TXCT23, PV-TXCT24, PV-TXCT25, and PV-TXCT26.

* Non-transgenic Bobwhite.

Plot design:

* Each plot will consist of one to four rows, 4-12 inches apart and up to 20 feet long.

* A standard experimental design will be utilized such as a randomized complete block design or a split plot design.

* The number of replications will be determined by seed availability. The anticipated number of replications is from one to four.

Space requirements:

* The transgenic material will cover less than 1.0 acre with no more than 500,000 plants.

* The experiment including the border will cover less than 1.2 acres.

* The total area needed for the entire test (including borders and alleyways) will be no greater than 1.5 acres.

Isolation:

This trial will be isolated from other wheat according to the standards set forth by Association of Official Seed Certifying Agencies in the "Certification Handbook." In using these guidelines for reference, the wheat in this trial will be separated from other wheat by a 20 foot strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat.

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CONTAINS C B I

Tentative schedule:

* Planting: March 15 to May 15 depending on weather and seed availability.

* Harvest: July 1 to August 31 depending on weather and date of planting.

Agronomic practices:

* Ground preparation and fertility: Ground prepartion will follow normal practices for wheat. Fertilizer may be applied based on a soil test to bring the nutrient level up to that recommended for wheat. Additional fertilizer may be applied throughout the season as needed.

* Weed control: Weed control will follow acceptable practices for wheat by using labelled herbicides, experimental herbicides, and/or hand weeding.

* Disease control: Diseases will be controlled by the use of labelled fungicides for seed treatment and/or topical applications.

* Insect control: Insect pests will be monitored for their appearance in the field. Insecticides labelled to control insect pests that are present will be applied as needed, including seed treatments or topical applications.

Harvest procedures:

* The wheat will be harvested by hand or with a field plot harvester. If a machine is used, it will be thoroughly cleaned prior to exiting the plot area.

Plant and seed disposal:

* Some seed will be sent to Monsanto laboratories in Chesterfield, MO for further analysis. After data collection and harvest, all remaining seed not sent to Monsanto will be either clearly marked and stored in a secure facility at the site or destroyed on the site by distribution in the field. The seed and remaining plant stubble will be mechanically incorporated into the soil. After the experiment is concluded, the plot area will be monitored for 8 months for germinating seed which will be destroyed with tillage or herbicide treatment.

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CONTAINS C B I

SITE SPECIFIC INFORMATION

(b) (6), (b) (7)(C), (b) (4) **Montana**
Yellowstone County

Principle Investigator: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) MT (b) (6), (b) (7)(C), (b) (4)
tel: (b) (6), (b) (7)(C), (b) (4)
fax:

Site Description:

(b) (6), (b) (7)(C), (b) (4) The surrounding area is utilized as farmland and dairy. Predominant crops grown within the valley include barley and sugarbeet in continuous cropping cycles.

Principle Investigator: (b) (6), (b) (7)(C)
The Agriculture Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
phone: (b) (6), (b) (7)(C)
FAX: (314) 537-6950

Site Description:

(b) (6), (b) (4), (b) (7)(C)

Item 13f. All research and procedures used in the production of the donor organism, recipient organism, vector or vector agent and the transgenic wheat were done utilizing level BL2 containment according to the NIH Guidelines for Recombinant DNA Research. All transgenic plants and their clonally propagated "progeny" have been repeatedly tested, and do not contain *Agrobacterium* cells.

Items 13g and h: None of the wheat seed or plant material produced in this experiment will enter commerce or will be consumed by domestic animals.

Seed will be taken to the field sites in containers fastened to preclude spillage. Movement will be in an enclosed vehicle. Up to three movements to each field site are anticipated. There will be up to 20 pounds of seed totaled over the three movements to each site. Movements should occur from March 1 - July 1, 1995.

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CONTAINS C B I

Isolation:

This trial will be isolated from other wheat according to the standards set forth by Association of Official Seed Certifying Agencies in the "Certification Handbook." In using these guidelines for reference, the wheat in this trial will be separated from other wheat by a 20 foot strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat.

Harvest:

Plots will be harvested, either by hand or by machine. If a machine is used, it will be thoroughly cleaned prior to exiting the plot area.

Item 13i. Following harvest, some seed will be sent to Monsanto laboratories in Chesterfield, Missouri for further analysis. After data collection and harvest, all remaining seed not sent to Monsanto will be either clearly marked and stored in a secure facility on site or destroyed on the site by distribution in the field. The seed and remaining plant stubble will be mechanically incorporated into the soil.

After the experiment is concluded, the plot area will be monitored for one year for plants. Any such volunteers will be killed through cultivation and/or herbicide treatment.

RECEIVED

OR120018_BR_011743

CBI DELETED
95-010-02

INFORMATION SUBMITTED TO THE UNITED STATES DEPARTMENT OF AGRICULTURE IN SUPPORT OF AN APPLICATION TO FIELD TEST

TESTING OF MARKER GENES IN GENETICALLY ENGINEERED WHEAT PLANTS

94-247PR

January 9, 1994

Volume 1 of 1

Report Compiled by:
(b) (6), (b) (7)(C)

Confidential Business Information Deleted

MONSANTO AGRICULTURAL COMPANY
700 Chesterfield Parkway North • St. Louis • Missouri • 63198

OR120018_BR_011744

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APHIS FORM 2000 ATTACHMENTS

This request for a Release into the Environment Permit is to allow the field testing of marker genes in genetically modified wheat at the locations specified in item 10. All of the information required to support this application is found in this volume.

The vector constructs that may be a part of this field experiment are:

PV-TXSM08, PV-TXSM09, PV-TXCT16, PV-TXCT17, PV-TXCT18, PV-TXSM10, PV-TXCT19, PV-TXCT20, PV-TXCT21, PV-TXCT22, PV-TXCT23, PV-TXCT24, PV-TXCT25, and PV-TXCT26.

Item 6. The following is the information required to identify the donor, recipient, and regulated organisms and vector agent:

a) For Event PV-TXSM08:

	Scientific Name	Common Name
a. Donor Organism	[**CBI DELETED**] [**CBI DELETED**]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

b) For Event PV-TXSM09:

	Scientific Name	Common Name
a. Donor Organism	[**CBI DELETED**] [**CBI DELETED**]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

c) For Cotransformation Event PV-TXCT16:

Plasmid vector PV-TXSM09:

See description above.

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Plasmid vector PV-TXSM06:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

d) For Cotransformation Event PV-TXCT17:

Plasmid vector PV-TXSM09:

See description above.

Plasmid vector PV-TXSM01:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

e) For Cotransformation Event PV-TXCT18:

Plasmid vector PV-TXSM08:

See description above.

Plasmid vector PV-TXSM06:

See description above.

OR120018_BR_011746

C B I DELETED

f) For Event PV-TXSM10:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] [CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

g) For Cotransformation Event PV-TXCT19:

Plasmid vector PV-TXSM10:

See description above.

Plasmid vector PV-TXSM06:

See description above.

h) For Cotransformation Event PV-TXCT20:

Plasmid vector PV-TXSM11:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] [CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM06:

See description above.

OR120018_BR_011747

CBI DELETED

i) **For Cotransformation Event PV-TXCT21:**

Plasmid vector PV-TXSM11:

See description above.

Plasmid vector PV-TXSM09:

See description above.

j) **For Cotransformation Event PV-TXCT22:**

Plasmid vector PV-TXSM12:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] [CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid vector PV-TXSM06:

See description above.

k) **For Cotransformation Event PV-TXCT23:**

Plasmid vector PV-TXSM12:

See description above.

Plasmid vector PV-TXSM09:

See description above.

OR120018_BR_011748

CBI DELETED

l) **For Cotransformation Event PV-TXCT24:**

Plasmid vector PV-TXSM12:

See description above.

Plasmid vector PV-TXSM07:

	Scientific Name	Common Name
a. Donor Organism	[CBI DELETED] [CBI DELETED]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

m) **For Cotransformation Event PV-TXCT25:**

Plasmid vector PV-TXSM11:

See description above.

Plasmid vector PV-TXSM04:

	Scientific Name	Common Name
a. Donor Organism	Tn5	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

n) **For Cotransformation Event PV-TXCT26:**

Plasmid vector PV-TXSM12:

See description above.

Plasmid vector PV-TXSM04:

See description above.

OR120018_BR_011749

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM08

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CMP1/[ ] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[

CBI DELETED

]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.
[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011750

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
[

CBI DELETED

]

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.
[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011751

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT16

PV-TXSM09 AND PV-TXSM06 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011752

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM06

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

Herbicide Tolerance Marker Gene 1 Expression of this gene in plant cells serves as a selectable marker for transformation.

[

CBI DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011753

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT17

PV-TXSM09 AND PV-TXSM01 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

OR120018_BR_011754

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.
[
CBI DELETED
]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011755

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT18

PV-TXSM08 AND PV-TXSM06 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM08

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CMP1/[ ] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

See description above.

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011756

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM06

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

Herbicide Tolerance Marker Gene 1 Expression of this gene in plant cells serves as a selectable marker for transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011757

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM10

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.
[
CBI DELETED
]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011758

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT19

PV-TXSM10 AND PV-TXSM06 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM10

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011759

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM06

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

Herbicide Tolerance Marker Gene 1 Expression of this gene in plant cells serves as a selectable marker for transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011760

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT20

PV-TXSM11 AND PV-TXSM06 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM11

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

TSP2/[ ] The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.
[

CBI DELETED

]

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

TSP2/[ ] The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011761

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM06

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

Herbicide Tolerance Marker Gene 1 Expression of this gene in plant cells serves as a selectable marker for transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011762

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT21

PV-TXSM11 AND PV-TXSM09 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM11

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

TSP2/[ ] The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

TSP2/[ ] The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011763

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011764

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT22

PV-TXSM12 AND PV-TXSM06 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM12

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

TSP3/[ ] The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.
[

CBI DELETED

]

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

TSP3/[ ] The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011765

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM06

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

Herbicide Tolerance Marker Gene 1 Expression of this gene in plant cells serves as a selectable marker for transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011766

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT23

PV-TXSM12 AND PV-TXSM09 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM12

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

TSP3/[ ] The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

TSP3/[ ] The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011767

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011768

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT24

PV-TXSM12 AND PV-TXSM07 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM12

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

TSP3/[ ] The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

TSP3/[ ] The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011769

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM07

This construct is a free delivery: pUC-Kan vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

Herbicide Tolerance Marker Gene 1 Expression of this gene in plant cells serves as a selectable marker for transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011770

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT25

PV-TXSM11 AND PV-TXSM04 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM11

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

TSP2/[ ] The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

TSP2/[ ] The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011771

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807). NPTII is a 0.83 Kb neomycin phosphotransferase typeII gene from TN5.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011772

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT26

PV-TXSM12 AND PV-TXSM04 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

CONSTRUCT DESCRIPTION FOR PV-TXSM12

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

TSP3/[ ] The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

AS1 Expression of this sequence alters the expression of marker genes.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

TSP3/[ ] The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

See description above.

TMG1 The expression of this gene is used as a marker for plant transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011773

C B I DELETED

CONSTRUCT DESCRIPTION FOR PV-TXSM04

This construct is a free delivery: pUC-Kan vector containing 1 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CMoVa/[ ] A caulimovirus promoter plus intron.

See description above.

NPTII Expression of this gene in plant cells confers resistance to kanamycin and serves as a selectable marker for transformation.

See description above.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene.

See description above.

OR120018_BR_011774

CBI DELETED

Item 9: The donor, recipient and vector organisms were collected in the United States. The vector construct and transgenic wheat were developed by Monsanto at the Chesterfield Village Laboratories. The planting material will be wheat seeds produced by and shipped from:

(b) (6), (b) (7)(C)
The Agricultural Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
Tel.: (b) (6), (b) (7)(C)
Fax: 314-537-6950

Item 10. The locations of the field experiment is as follows (2):

(b) (6), (b) (7)(C), (b) (4) **Illinois**
Jersey County

Principle Investigator: (b) (6), (b) (7)(C)
The Agricultural Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
Tel.: (b) (6), (b) (7)(C)
Fax: 314-537-6950

(b) (6), (b) (7)(C), (b) (4) **Montana**
Yellowstone County

Principle Investigator: (b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) MT (b) (6), (b) (7)(C), (b) (4)
tel: (b) (6), (b) (7)(C), (b) (4)

Item 13a. The transgenic wheat which is the subject of this permit request, was developed by scientists at Monsanto. For additional information contact the applicant of this permit.

Item 13b. The transgenic material that is the recipient of the added genes is the CIMMYT(Centro Internaclonal de Mejoramiento de Maiz y Trigo, Facimile 52-595-41069) line Bobwhite. The line Bobwhite was designated to a group of advanced lines derived from the cross Aurora/Kalyan/Bluebird/3/Woodpecker CM33203. This cross was made at CIMMYT in 1973.

Bobwhite is in general semidwarf, carries resistance to septoria tritici, leaf rust, and the gene YR9 for stripe rust. The Bobwhite lines carry the 1B/1R translocation i.e. 1BS is translocated by 1RS of rye. The 1B/1R was derived from the variety Aurora from the USSR. Despite the fact that it carries 1B/1R translocation associated with poor quality(stickiness), industrial quality of Bobwhite is good, and acceptable in most countries.

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The Bobwhite line has been genetically -modified by particle bombardment for co-transformation of one of the scorable or selectable markers described . At present no molecular or segregation data is available from the lines that will be evaluated in the field trial. However the original transformed plants have been qualitatively evaluated for gene expression of the selectable marker/s with positive results.

Item 13c. The description of the plasmid vector as inserted into these wheat plants is as follows:

VECTOR DESCRIPTION FOR FREE DELIVERY

Free delivery vectors are engineered to contain multiple chimeric plant expression genes in either the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11) or pMON 10081, a derivative of the high copy *E. coli* plasmid pUC119. These vectors contain either the B-lactamase gene conferring bacterial ampicillin resistance (pUC119) or the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance (pMON 10081). The antibiotic markers are driven by bacterial promoters which do not contain the regulatory elements necessary to express in plants. They are also used to propagate the plasmid in *E. coli* in order to produce sufficient DNA quantities for transformation experiments (further described in Delivery System Description).

FREE DELIVERY PARTICLE GUN (MONSANTO)

Introduction of DNA into plant tissue with the "biolistic" particle bombardment method has been described in detail by Klein et al. (1987, Nature 327: 70-73; 1988a, Bio/Technology 6: 559-563; and 1988b, Proc Natl Acad Sci USA 85: 4305-4309). The transgenic material in this application was produced using the commercially available particle delivery systems. Detailed instructions are available from the manufacturers. Briefly, DNA is precipitated onto microscopic (~1 μ diameter) tungsten or gold particles using calcium chloride and spermidine. A drop (2.5μl) of the coated particles is accelerated at a high velocity allowing the particles to penetrate the target plant cells, where the DNA is deposited and incorporated into the plant cell genome. The cells are incubated on a tissue culture medium which supports the growth of embryogenic callus. The introduced DNA contains a gene(s) encoding for resistance to either antibiotics (e.g., the NPTII gene for resistance to kanamycin and G418) or genes conferring herbicide resistance. The plant cells are grown in the presence of an appropriate antibiotic or herbicide, and only the transformed cells continue to grow. Plants are regenerated from the resistant embryogenic callus tissue, and are assayed for the presence of the introduced gene(s). The free delivery vectors are engineered to contain multiple chimeric plant expression genes in high copy E. coli plasmids.

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VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Amp

The free delivery vectors are engineered to contain multiple chimeric plant expression genes in the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). The pUC119 plasmid contains the ß-lactamase gene conferring bacterial ampicillin resistance. Several chimeric plant expression genes can be introduced into pUC119. These include the marker genes required for selection of the transformed plant tissue, and one or more genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Kan

The free delivery vectors contain multiple chimeric plant expression genes engineered into pMON10081. The pMON10081 plasmid is a derivative of the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). It was constructed by fusing the 1.3 Kb FspI-DraI origin of replication fragment from pUC119, to the 1.3 Kb SmaI-HindIII (Klenow filled) fragment from pKC7 (Rao and Rogers 1979, Gene 7: 79). The pKC7 fragment contains the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance. The ß-lactamase gene conferring bacterial ampicillin resistance was completely deleted. Several chimeric plant expression genes can be introduced into pMON10081. These include the marker genes required for selection of the transformed plant tissue, and one or more chimeric genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

Item 13d. The plasmid vectors were constructed at the research laboratories of Monsanto Co. in St. Louis, Missouri. The initial wheat plants transformed with these vectors were also developed at the research laboratories of Monsanto Co. in St. Louis, Missouri, USA.

Item 13e. The information regarding the description of the propose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design is found in the protocol on the following page.

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PROPOSED EXPERIMENTAL PROGRAM

MARKER GENES IN GENETICALLY MODIFIED WHEAT

Purpose of the test:

To test the efficacy of various marker genes in wheat.

Investigators:

* Principal Monsanto investigator at (b) (4) MO and for (b) (6), (b) (7)(C), (b) (4) Illinois field site:

(b) (6), (b) (7)(C)
(b) (4)
(b) (4) MO (b) (4)
phone: (b) (6), (b) (7)(C)
FAX: (b) (4)

* Principal investigator at Billings, Montana field site:

(b) (6), (b) (7)(C), (b) (4)
(b) (6), (b) (7)(C), (b) (4) MT (b) (6), (b) (7)(C), (b) (4)
phone: (b) (6), (b) (7)(C), (b) (4)

Field Test Design:

* The test will use an experimental design that best addresses the test objectives while dealing with limited seed quantities.

* Treatments will be chosen from the following:

    * Chemical herbicide: Use of commercially available herbicides or proprietary chemistry to evaluate the effects of application on weed control and crop tolerance.

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* Timing of application: Chosen from growth stages between emergence through first flowering including sequential applications at two or more growth stages.

* Type of application: Over-the-top or post-directed.

Genotypes:

* Homozygous and segregating progeny of lines transformed with one of the following vectors:

  PV-TXSM08, PV-TXSM09, PV-TXCT16, PV-TXCT17, PV-TXCT18, PV-TXSM10, PV-TXCT19, PV-TXCT20, PV-TXCT21, PV-TXCT22, PV-TXCT23, PV-TXCT24, PV-TXCT25, and PV-TXCT26.

* Non-transgenic Bobwhite.

Plot design:

* Each plot will consist of one to four rows, 4-12 inches apart and up to 20 feet long.

* A standard experimental design will be utilized such as a randomized complete block design or a split plot design.

* The number of replications will be determined by seed availability. The anticipated number of replications is from one to four.

Space requirements:

* The transgenic material will cover less than 1.0 acre with no more than 500,000 plants.

* The experiment including the border will cover less than 1.2 acres.

* The total area needed for the entire test (including borders and alleyways) will be no greater than 1.5 acres.

Isolation:

This trial will be isolated from other wheat according to the standards set forth by Association of Official Seed Certifying Agencies in the "Certification Handbook." In using these guidelines for reference, the wheat in this trial will be separated from other wheat by a 20 foot strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat.

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Tentative schedule:

* Planting: March 15 to May 15 depending on weather and seed availability.

* Harvest: July 1 to August 31 depending on weather and date of planting.

Agronomic practices:

* Ground preparation and fertility: Ground prepartion will follow normal practices for wheat. Fertilizer may be applied based on a soil test to bring the nutrient level up to that recommended for wheat. Additional fertilizer may be applied throughout the season as needed.

* Weed control: Weed control will follow acceptable practices for wheat by using labelled herbicides, experimental herbicides, and/or hand weeding.

* Disease control: Diseases will be controlled by the use of labelled fungicides for seed treatment and/or topical applications.

* Insect control: Insect pests will be monitored for their appearance in the field. Insecticides labelled to control insect pests that are present will be applied as needed, including seed treatments or topical applications.

Harvest procedures:

* The wheat will be harvested by hand or with a field plot harvester. If a machine is used, it will be thoroughly cleaned prior to exiting the plot area.

Plant and seed disposal:

* Some seed will be sent to Monsanto laboratories in Chesterfield, MO for further analysis. After data collection and harvest, all remaining seed not sent to Monsanto will be either clearly marked and stored in a secure facility at the site or destroyed on the site by distribution in the field. The seed and remaining plant stubble will be mechanically incorporated into the soil. After the experiment is concluded, the plot area will be monitored for 8 months for germinating seed which will be destroyed with tillage or herbicide treatment.

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SITE SPECIFIC INFORMATION

(b) (6), (b) (7)(C), (b) (4) **Montana**
Yellowstone County

Principle Investigator: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) MT (b) (6), (b) (7)(C), (b) (4)

tel: (b) (6), (b) (7)(C), (b) (4)
fax:

Site Description:

(b) (6), (b) (7)(C), (b) (4) The surrounding area is utilized as farmland and dairy. Predominant crops grown within the valley include barley and sugarbeet in continuous cropping cycles.

Principle Investigator: (b) (6), (b) (7)(C)

The Agriculture Company of Monsanto
700 Chesterfield Parkway North
St. Louis, MO 63198
phone: (314) 537-6642
FAX: (314) 537-6950

Site Description:

REDACTED

Item 13f. All research and procedures used in the production of the donor organism, recipient organism, vector or vector agent and the transgenic wheat were done utilizing level BL2 containment according to the NIH Guidelines for Recombinant DNA Research. All transgenic plants and their clonally propagated "progeny" have been repeatedly tested, and do not contain *Agrobacterium* cells.

Items 13g and h: None of the wheat seed or plant material produced in this experiment will enter commerce or will be consumed by domestic animals.

Seed will be taken to the field sites in containers fastened to preclude spillage. Movement will be in an enclosed vehicle. Up to three movements to each field site are anticipated. There will be up to 20 pounds of seed totaled over the three movements to each site. Movements should occur from March 1 - July 1, 1995.

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Isolation:

This trial will be isolated from other wheat according to the standards set forth by Association of Official Seed Certifying Agencies in the "Certification Handbook." In using these guidelines for reference, the wheat in this trial will be separated from other wheat by a 20 foot strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat.

Harvest:

Plots will be harvested, either by hand or by machine. If a machine is used, it will be thoroughly cleaned prior to exiting the plot area.

Item 13i. Following harvest, some seed will be sent to Monsanto laboratories in Chesterfield, Missouri for further analysis. After data collection and harvest, all remaining seed not sent to Monsanto will be either clearly marked and stored in a secure facility on site or destroyed on the site by distribution in the field. The seed and remaining plant stubble will be mechanically incorporated into the soil.

After the experiment is concluded, the plot area will be monitored for one year for plants. Any such volunteers will be killed through cultivation and/or herbicide treatment.

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DRAFT

APPLICATION NUMBER	APPLICANT	DATE RECEIVED	ORGANISMS	FIELD TEST LOCATION
95-010-01	Monsanto Company	01/10/95	Wheat plants genetically engineered to express genes for fungal resistance.	Illinois
95-010-02	Monsanto Company	01/10/95	Wheat plants genetically engineered to express various marker genes.	Illinois, Montana

OR120018_BR_011783

FILE COPY

APHIS APPLICATION NO. 95-010-02r
DATE: 3/7/95

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

X State concurs with APHIS' initial review.

_____ State concurs with APHIS' initial review and offers the following comments (use additional sheets if necessary):

_____ State does not concur with APHIS' initial review and offers the following reasons for nonconcurrence (use additional sheets if necessary):

Name of State Official: STAN SMITH

Title: Supervisor

Agency or Department: Ill Dept Agriculture

Address: 9511 Harrison St

City, State, Zip Code: Des Plaines, IL 60016

Signature: (b) (6), (b) (7)(C)

Date: 3/23/95

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

DR. SUSAN KOEHLER
USDA, APHIS, BBEP
Biotechnology Permits, FB Room 843
6505 Belcrest Road
Hyattsville, MD 20782

RECEIVED 3/28/95

3/28/95

OR120018_BR_011784

FILE COPY

APHIS APPLICATION NO. 95-010-02r
DATE: 3/7/95

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

__X__ State concurs with APHIS' initial review.

_____ State concurs with APHIS' initial review and offers the following comments (use additional sheets if necessary):

_____ State does not concur with APHIS' initial review and offers the following reasons for nonconcurrence (use additional sheets if necessary):

Name of State Official: BARBRA MULLIN

Title: Weed Specialist

Agency or Department: MT Dept of Agriculture
AGD-TSB

Address: PO Box 200201

City, State, Zip Code: Helena MT 59620

Signature: (b) (6), (b) (7)(C)

Date: 24 Mar 95

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

DR. SUSAN KOEHLER
USDA, APHIS, BBEP
Biotechnology Permits, FB Room 843
6505 Belcrest Road
Hyattsville, MD 20782

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4/3/95 AG

BBO Ltr eg

Calgene, Inc
1920 Fifth Street
Davis, CA 95616
ph 916-753-6313
fx 916-753-2764

PLEASE NOTIFY OR DISTRIBUTE AS SOON AS POSSIBLE

Please notify M. Miller if you do not receive all _____ pages including this cover sheet

RECEIVED 8/8/95

HARVEST REPORT

This fax is being sent to the following persons, please cc the appropriate person for your agency.

USDA	Dave Heron	301-734-8669
	Ralph Stoaks	916-857-6100
State Regulators	Barbara Hass	916-654-1018
	Nicolas Coronel	619-357-8159
	Danny Hamon	209-472-1074
	Don Dougherty	916-342-0852
Calgene	Keith Redenbaugh	
	Matti Sovero	
	Tony Ballmann	

JUL-26-95 WED 12:08 CALGENE FAX NO. 9167532764 P. 01/02

OR120018_BR_011786

P. 02/02
FAX NO. 9167532764
CALGENE
JUL-26-95 WED 12:08

Harvest and Trial Destruction Notification Report

7/26/95

Calgene, Inc.
ph 800-992-4363 fx 916-753-1510

Contact M. Miller if transmission incomplete

Crop	Permit #	State	County	Estimated Date [Earliest]	Estimated Date [Latest]	Actual Harvest Date	Destruction Date	To schedule inspection contact:		Date USDA inspection scheduled
Rapeseed	95-01-02 95-010-02	CA	Sonoma			* 7/26/95		Tony Ballmann	916-753-6313	

* Some single plant harvesting was done on some plants that had prematurely dried down. Harvest will continue through the next 3 weeks.

Destruction Method - Option #2 Rotation. Field disked and to be rotated to another crop and monitored regularly

OR120018_BR_011787

Monsanto 95-010-02

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

January 9, 1995

Att: E. Dianne Hatmaker
Cheif, Permits Branch
Biotechnology Permits
Biotechnology, Biologics, and Environmental Protection
6505 Belcrest Rd, Suite 7
Hyattsville, MD 20782
FAX: 301-436-8910

Subject: Request for a Permit to Field Test Marker Genes in Wheat

Dear Ms. Hatmaker:

Monsanto Agricultural Company is requesting a permit from USDA to allow wheat which has been genetically modified for the expression of marker genes to be tested in Illinois and Montana.

In support of this request for a permit to allow release into the environment, please find the completed APHIS Form 2000 attached to this letter. In addition we are submitting 1 copy of the application containing the required information to support this request. This volume contains confidential business information (CBI) and is so marked on the cover and each place within the volume where the CBI occurs. As required, we are also submitting 1 copy of this same material with all CBI deleted.

This confidential information was developed by Monsanto at its own expense, has not been released to anyone not under a secrecy agreement to Monsanto and has not been published. We request that this information not be released as it has value to our competitors (domestic and foreign) in that they would be able to copy this work and unfairly compete with us causing financial loss and other harm to Monsanto.

We appreciate your attention to this matter. Should you have any questions, please feel free to contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

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DISTRIBUTION

	CBI	CBI Deleted
USDA	1 Copy	1 Copy
State of Montana	-	1 Copy
State of Illinois	-	1 Copy
(b) (6), (b) (7)(C)	1 Copy	-
	1 Copy	-
REGISTRATION FILES	1 Copy	1 Copy

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TABLE OF CONTENTS

	page
VOLUME 1	
APHIS FORM 2000	
APHIS FORM 2000 ATTACHMENTS	1

OR120018_BR_011790

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (IOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (IOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

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The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.[1]

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of marker genes in plants and their use in insect and virus resistant and herbicide tolerant crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

1 In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

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To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Calgene, Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

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Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for wheat has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

OR120018_BR_011794

ATTACHMENT
CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION
MARKER GENES IN WHEAT

Page	Category of Information	Justification
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
1	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
2	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
3	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

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3	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
4	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
5	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011796

8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
13	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
14	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
14	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
14	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011797

15	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
15	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
16	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
17	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
17	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
17	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
18	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
19	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
19	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
20	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
21	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

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21	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
21	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
22	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
23	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
23	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
24	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
25	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
25	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
26	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
26	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
27	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011799

27	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
28	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
29	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
29	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
30	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011800

FILE COPY

(b) (6), (b) (7)(C)
Monsanto Agricultural Products
600 Chesterfield Village Parkway
St. Louis, MO 63198

January 30, 1995

Dear (b) (6), (b) (7)(C)

This is in response to your permit applications received, January 10, 1995, for release into the environment under 7 C.F.R. Part 340.

The application for a permit to conduct a field test of genetically engineered wheat plants that express fungal resistant genes, has been assigned application number 95-010-01. The technical reviewer assigned to this application is Dr. Vedpal Malik.

The application for a permit to conduct a field test of genetically engineered wheat plants that express marker genes, has been assigned application number 95-010-02. The technical reviewer assigned to this application is Dr. Susan Koehler.

Please refer to these numbers in correspondence that pertains to these applications. You will be contacted if further information is needed for these permit application reviews.

A notice will be published in the Federal Register informing the public of the Animal and Plant Health Inspection Service's (APHIS) receipt of your applications. The non-confidential business information copy of your applications will be made available to the public through the APHIS Reading Room as specified in the Federal Register, through the Biotechnology Permits Office, and through the Freedom of Information Act Office.

Some States have separate regulations pertaining to release and movement of genetically engineered organisms, therefore it is recommended that you submit your applications to the appropriate States at the same time it is submitted to APHIS. This allows the States adequate time to review the applications and respond promptly to APHIS' preliminary assessment.

Please call our office at Area Code (301) 436-7612 if you have questions or if we can be of assistance. Thank you for your cooperation.

Sincerely,

Clayton Givens
Program Assistant
Biotechnology Program Operations
cc: permit application file : 95-010-01 and 94-010-02.

OR120018_BR_011801

FILE COPY

MAR 0 7 1995

Mr. Stanley E. Smith, Supervisor
State of Illinois Department of Agriculture
CMS North Suburban
9511 Harrison Street, Room A169
Des Plaines, IL 60016

Re: APHIS Review of the Monsanto Company Application to Field Test Genetically Engineered Wheat Plants; Accession Number 95-010-02r

Dear Mr. Smith:

This letter contains our review of an application submitted by Monsanto Company for a permit that would allow the field testing of genetically engineered wheat plants. The wheat plants were genetically engineered to express certain selectable and scoreable marker genes. The field tests are scheduled to take place from March 15, 1995 to December 31, 1995. The proposed field tests are to be carried out in two states, Illinois (Jersey County) and Montana (Yellowstone County).

This application was submitted pursuant to regulations found in 7 CFR Part 340 which regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products which are regulated articles. The regulations, which were promulgated pursuant to authority granted by the Federal Plant Pest Act and Plant Quarantine Act, require that a person obtain a permit from the Animal and Plant Health Inspection Service (APHIS) prior to introducing a regulated article.

For purposes of this submission, these genetically engineered wheat plants are deemed "regulated articles" (as defined in §340.1 of the regulations) because they contain DNA sequences that were derived from plant pests. Under the regulations, one basis for designating an organism as a regulated article is that it is genetically engineered (as defined in §340.1) from a donor organism, recipient organism, or vector or vector agent, which is listed in §340.2 of the regulations, and the listed organism is a plant pest (as defined in §340.1).

These plants are deemed regulated articles because certain nucleic acids sequences derived from known plant pests (*Agrobacterium tumefaciens*, and cauliflower mosaic virus) have been inserted into the plant's chromosome.

Pursuant to the procedures set forth in §340.3 of the regulations, we have prepared our assessment in this letter for your notification and review. This serves to give notice to the state and to provide the

OR120018_BR_011802

opportunity for the State to expressly indicate concurrence or nonconcurrence with our review. Please review the enclosed application documents and return acknowledgement, associated comments, and concurrence or reasons for nonconcurrence (if applicable) to APHIS within 30 days from the date of this letter.

Please use the enclosed form, and use additional sheets if needed for your response. It is very important that our office receive comments and opinions from State regulatory officials regarding the issuance of permits for the release of genetically engineered organisms into the environment.

On the basis of our review of this application, we have concluded that the controlled field testing of these genetically engineered wheat plants will not present any risk of plant pest introduction or dissemination for the reasons cited below.

1. Environmental Impacts Related to the Recipient. There appears to be little risk of the transgenic plant material or the introduced genes escaping the test site or surviving independently after termination of the experiment. Standard breeding practices, including the use of border rows and appropriate isolation distances, will be used to prevent mechanical mixing and unwanted introduction of transgenic material into neighboring wheat plants via pollen. Wheat is normally self-pollinated. The trial will be isolated from other wheat according to the standards set forth by the Association of Official Seed Certifying Agenicies, i.e., by a 20 ft. strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat. Harvesting equipment, if used, will be thoroughly cleaned prior to leaving the area.

2. Environmental Impacts Related to the Donor. The transgenic wheat lines have been engineered with various combinations of selectable and scoreable marker genes. These include those conferring resistance to the antibiotic kanamycin, those conferring tolerance to the herbicide glyphosate and another herbicide, and a different class of scoreable marker. The *nptII* gene conferring resistance to the antibiotic kanamycin encodes the enzyme neomycin phosphotransferase. All of these marker genes are used to facilitate the selection of transformed plant tissue either in the laboratory or in the field. Some of the transgenic wheat lines have also been genetically engineered to express gene constructs which alter the expression of the marker genes. Although some DNA sequences were derived from plant pathogens, none of the introduced genes nor the regulatory sequences used to express these genes have any inherent pest characteristics or pose a risk to plant health.

3. Environmental Impacts Related to the Vector and Vector Agent. The genes were transferred to wheat via the "biolistic" particle bombardment method. This is a well characterized transformation

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system which integrates the donor genes into the chromosome of the recipient plant cell. These donor sequences then are maintained and inherited as any other genes of the plant cell.

4. Quarantine of Organism and Final Disposition. The test site is expected to provide adequate physical security. Site monitoring and management practices that create a nonpropagative environment should provide the necessary degree of both biological and physical containment. Following harvest, seed not sent to Monsanto laboratories or stored securely on site will be distributed on the field plots. The field plots will be disced to destroy plants and incorporate stuble and seeds. The plots will be monitored for volunteer plants for one year. Volunteer plants will be destroyed by discing and/or herbicide treatment. The containment measures described in the application should be sufficient to prevent any unplanned releases of the transgenic plant material.

Staff Contact

If you have any questions about this application or our review, please contact Dr. Susan Koehler, Biotechnologist, at Area Code (301) 734-4886 or facsimile number (301) 734-8669. Please refer to permit application number 95-010-02r in your correspondence regarding this application. APHIS hopes to maintain its excellent working relationship with your State and encourages your participation and comments prior to our final decision.

Sincerely,

/s/ S. Shantharam

Sivramiah Shantharam, Ph.D.
Chief, Microorganisms Branch
Biotechnology Permits

2 Enclosures
Permit Application 95-010-02r
State Response Form

cc:
J. Burch, PPQ, Moorestown, NJ
File 95-010-02

APHIS:BBEP:BP:SKOEHLER:RAS:734-7612:3/3/95:9501002R.SIL

OR120018_BR_011804

MAR 0 7 1995

Mr. William Kissinger, Administrator
Plant Industry Division
Montana Department of Agriculture
Agriculture/Livestock Building
P.O. Box 200201
Helena, MT 59620

Re: APHIS Review of the Monsanto Company Application to Field Test Genetically Engineered Wheat Plants; Accession Number 95-010-02r

Dear Mr. Kissinger:

This letter contains our review of an application submitted by Monsanto Company for a permit that would allow the field testing of genetically engineered wheat plants. The wheat plants were genetically engineered to express certain selectable and scoreable marker genes. The field tests are scheduled to take place from March 15, 1995 to December 31, 1995. The proposed field tests are to be carried out in two states, Illinois (Jersey County) and Montana (Yellowstone County).

This application was submitted pursuant to regulations found in 7 CFR Part 340 which regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products which are regulated articles. The regulations, which were promulgated pursuant to authority granted by the Federal Plant Pest Act and Plant Quarantine Act, require that a person obtain a permit from the Animal and Plant Health Inspection Service (APHIS) prior to introducing a regulated article.

For purposes of this submission, these genetically engineered wheat plants are deemed "regulated articles" (as defined in §340.1 of the regulations) because they contain DNA sequences that were derived from plant pests. Under the regulations, one basis for designating an organism as a regulated article is that it is genetically engineered (as defined in §340.1) from a donor organism, recipient organism, or vector or vector agent, which is listed in §340.2 of the regulations, and the listed organism is a plant pest (as defined in §340.1).

These plants are deemed regulated articles because certain nucleic acids sequences derived from known plant pests (*Agrobacterium tumefaciens*, and cauliflower mosaic virus) have been inserted into the plant's chromosome.

Pursuant to the procedures set forth in §340.3 of the regulations, we have prepared our assessment in this letter for your notification and review. This serves to give notice to the state and to provide the

OR120018_BR_011805

opportunity for the State to expressly indicate concurrence or nonconcurrence with our review. Please review the enclosed application documents and return acknowledgement, associated comments, and concurrence or reasons for nonconcurrence (if applicable) to APHIS within 30 days from the date of this letter.

Please use the enclosed form, and use additional sheets if needed for your response. It is very important that our office receive comments and opinions from State regulatory officials regarding the issuance of permits for the release of genetically engineered organisms into the environment.

On the basis of our review of this application, we have concluded that the controlled field testing of these genetically engineered wheat plants will not present any risk of plant pest introduction or dissemination for the reasons cited below.

1. Environmental Impacts Related to the Recipient. There appears to be little risk of the transgenic plant material or the introduced genes escaping the test site or surviving independently after termination of the experiment. Standard breeding practices, including the use of border rows and appropriate isolation distances, will be used to prevent mechanical mixing and unwanted introduction of transgenic material into neighboring wheat plants via pollen. Wheat is normally self-pollinated. The trial will be isolated from other wheat according to the standards set forth by the Association of Official Seed Certifying Agenicies, i.e., by a 20 ft. strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat. Harvesting equipment, if used, will be thoroughly cleaned prior to leaving the area.

2. Environmental Impacts Related to the Donor. The transgenic wheat lines have been engineered with various combinations of selectable and scoreable marker genes. These include those conferring resistance to the antibiotic kanamycin, those conferring tolerance to the herbicide glyphosate and another herbicide, and a different class of scoreable marker. The *nptII* gene conferring resistance to the antibiotic kanamycin encodes the enzyme neomycin phosphotransferase. All of these marker genes are used to facilitate the selection of transformed plant tissue either in the laboratory or in the field. Some of the transgenic wheat lines have also been genetically engineered to express gene constructs which alter the expression of the marker genes. Although some DNA sequences were derived from plant pathogens, none of the introduced genes nor the regulatory sequences used to express these genes have any inherent pest characteristics or pose a risk to plant health.

OR120018_BR_011806

3. Environmental Impacts Related to the Vector and Vector Agent. The genes were transferred to wheat via the "biolistic" particle bombardment method. This is a well characterized transformation system which integrates the donor genes into the chromosome of the recipient plant cell. These donor sequences then are maintained and inherited as any other genes of the plant cell.

4. Quarantine of Organism and Final Disposition. The test site is expected to provide adequate physical security. Site monitoring and management practices that create a nonpropagative environment should provide the necessary degree of both biological and physical containment. Following harvest, seed not sent to Monsanto laboratories or stored securely on site will be distributed on the field plots. The field plots will be disced to destroy plants and incorporate stuble and seeds. The plots will be monitored for volunteer plants for one year. Volunteer plants will be destroyed by discing and/or herbicide treatment. The containment measures described in the application should be sufficient to prevent any unplanned releases of the transgenic plant material.

Staff Contact

If you have any questions about this application or our review, please contact Dr. Susan Koehler, Biotechnologist, at Area Code (301) 734-4886 or facsimile number (301) 734-8669. Please refer to permit application number 95-010-02r in your correspondence regarding this application. APHIS hopes to maintain its excellent working relationship with your State and encourages your participation and comments prior to our final decision.

Sincerely,

/s/ S. Shantharam

Sivramiah Shantharam, Ph.D.
Chief, Microorganisms Branch
Biotechnology Permits

2 Enclosures
Permit Application 95-010-02r
State Response Form

cc:
R. Stoaks, PPQ, Sacramento, CA
File 95-010-02

APHIS:BBEP:BP:SKOEHLER:RAS:436-7612:H:\9501002R.SMT

OR120018_BR_011807

FILE

APR 1 1 1995

(b) (6), (b) (7)(C)
Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Dear (b) (6), (b) (7)(C)

Subject: Biotechnology Permit Number 95-010-02 to Conduct a Planned Release of Genetically Engineered *Wheat* Plants

The above permit has been approved after a Finding of No Significant Impact (FONSI) and a finding that the genetically engineered organisms do not present a risk of plant pest introduction or dissemination. You must adhere to the standard and supplemental conditions enclosed.

This permit should not be taken as any type of efficacy determination of the genetically engineered organisms.

Sincerely,

/s/ S. Shantharam

Arnold S. Foudin, Ph.D.
Deputy Director
Biotechnology Permits

Enclosure:
Permit 95-010-02
Supplemental Permit Conditions
Standard Permit Conditions
Map - Regional Biotechnologists

cc:
S. Smith, IL Dept. of Agriculture, Des Plaines, IL
W. Kissinger, MT Dept. of Agriculture, Helena, MT
J. Burch, PPQ, Moorestown, NJ
R. Stoaks, PPQ, Sacramento, CA
S. Ingebritsen, BCTA, Riverdale, MD
File 95-010-02r

BP:BBEP:APHIS:SKOEHLER:RAS:734-7612:4/11/95:H:\9501002.IS

OR120018_BR_011808

1/22/96 10:37 am Release Tracking Sheet

FILE COPY

Bp number: 96-019-03r

Intro type: Release Renewal Permit:
Received: 1/19/96 Clock stop: Clock start: Due: 5/18/96
Institution: Monsanto
Resp person: (b) (6), (b) (7)(C)
Recipient: Wheat
Status: Pending Sites: 2 Acre:
Reviewer: VM
CBI status: CBI
Phenotype: HT - Glyphosate tolerant
Comments:
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 314-537-7085

		Initial	Date
1.	[✓] Assign Bp number and initial data entry	[CM]	[1/19/96]
2.	[ ] Letter of notification to Applicant	[ ]	[ ]
3.	[✓] File and this tracking sheet to reviewer	[CM]	[1/22/96]
4.	[ ] Letter of preliminary assessment to State	[CM]	[1/31/96]
5.	[ ] Reviewer checks data entries and returns this sheet to permit unit	[ ]	[ ]
6.	[ ] State response listed by State/Region/Sites		
	~~MN~~ SCR 1 State Response	[CM]	[4/22/96]
	WA WR 1 State Response	[CM]	[2/16/96]
7.	[ ] Permit issued or denied	[CM]	[4/22/96]
8.	[ ] Enter final data into database	[ ]	[ ]

Sent to MN 1/31

NO MN reply Rec'd

* State Ltr Sent 1/31/96

OR120018_BR_011809

1/22/96 10:38 am

Release Gene Data Entry Tracking Sheet

Reviewer of this sheet >>--> DH JW KR SG SK SS (VM) <--<< Please mark one
Problem >>-->

CURRENT IN DATABASE

Bp number: 96-019-03r	Intro type: Release	Renewal Permit:	Received:	1/19/96
Clock stop:	Clock start:	Due: 5/18/96	Issue/deny:	
Institution: Monsanto		Resp person: Serdy, Frank S.		
Recipient: Wheat				
Status: Pending	Sites: 2	Acre:	Reviewer: VM	CBI status: CBI
Location: ND WA				
Comments:				

Category: (HT)
Phenotype: Glyphosate tolerant

SM?:	Gene:	Donor:
SM	B-glucuronidase	E. coli

COMMON PREVIOUS ENTRIES AND COUNT FOR GENES, DONORS, AND PHENOTYPES

Category: AP BR (FR) (HT) IR MG NR OO PQ VR

Gene:	Donor:	Phentotype:
glucuronidase	E. coli	
AFP2		fungal diseases Antifungal protein gene 2
GME Syn	Achromobacter sp.	glyphosate tolerance
cp4	~~CP4~~ Agrobacterium	glyphosate tolerance

OR120018_BR_011810

This application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq. and the Plant Quarantine Act (7 U.S.C. 151 et seq.)). The information will be used to determine eligibility to receive all types of permits. No permit shall be issued until this application has been approved.

See reverse side for additional information

FORM APPROVED
OMB NO. 0579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

(Genetically Engineered Organisms or Products)

96-008PR

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

1. NAME AND ADDRESS OF APPLICANT

(b) (6), (b) (7)(C)
Monsanto Agricultural Group
700 Chesterfield Parkway North BB3A
Area Code Chesterfield, MO 63198

2. PERMIT REQUESTED ("X" one)

- ☐ Limited - Interstate Movement
- ☐ Limited - Importation
- ☒ Release into the Environment
- ☐ Courtesy Permit

3. THIS REQUEST IS ("X" one)

- ☒ New
- ☐ Renewal
- ☐ Supplemental

4. TELEPHONE NUMBER

96-019-03r

(b) (6), (b) (7)(C)

5. MEANS OF MOVEMENT

- ☐ Mail
- ☐ Baggage or Handcarried
- ☒ Common Carrier
- By whom _____

6. GIVE THE FOLLOWING *(if applicable) (if more space is needed, attach additional sheet)*

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism:				
b. Recipient Organism:	SEE ATTACHED			
c. Vector or Vector Agent:				
d. Regulated Organism or Product:				
e. If product, list names of constituents:				

7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS

SEE ATTACHED

8. DATE *(or inclusive dates of period)* **OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE**

SEE ATTACHED

9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

SEE ATTACHED

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

SEE ATTACHED

11. ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* **ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT**

NONE

12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

NOT APPLICABLE

13. SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON	15. PRINTED NAME AND TITLE	16. DATE
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	1/17/96

FOR APHIS USE ONLY

State Notification Sent	State Review Received	Permit Issued
January 31, 1996	WA = 2/16/96, MN = 4/22/96	☒ Yes ☐ No

Date of Determination	Permit No.	No. of Permit Labels Issued	Supplemental Conditions Enclosed
April 23, 1996	96-019-03r	n/a	☒ Yes ☐ No

Signature of BBEP Official	Date	Expiration Date
Arnold Foudin, Deputy Director, BP	April 23, 1996	April 23, 1997

OR120018_BR_011811

APHIS FORM 2000 (JUL 89) *Replaces PPQ Form 1001 which may be used.*

(continued on reverse)

Supplemental Permit Conditions

Permit Number 96-019-03r

1. Biotechnology, Biologics, and Environmental Protection (BBEP) or a Regional Biotechnologist will conduct an inspection of the test site at the beginning of the test. The permittee is required to notify the State regulatory official, and the appropriate Regional Biotechnologist (see attached map) at least 1-week before the test begins.

2. Additional inspections may be conducted by the Regional Biotechnologist. The permittee is required to notify the Regional Biotechnologist and the State Official at least 1-week before termination of the experiment.

3. A field test data report must be submitted within 12 months after the permit issuance date. If a field test is still in progress at 12 months or any multiple of 12 months after the permit issuance date, additional field test data reports must be submitted to APHIS and State Official within subsequent 12 month periods. Final reports for those field tests lasting more than 12 months must be submitted to APHIS and State Official 6 months after the termination of the field test. Field test reports shall include: methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment. We encourage the inclusion of other types of data if the applicant anticipates submission of a petition for determination of non-regulated status for their regulated article. APHIS views these data reports as critical to our assessment of plant pest risk and development of regulatory policies based on the best scientific evidence. Failure by an applicant to provide data reports in a timely manner for a field trial may result in the withholding of permission by APHIS for future field trials.

Confidential Business Information (CBI) will be handled according to the APHIS policy statement at 50 FR 38561-63.

4. The test site shall be monitored for any volunteer plants after the completion of the test until the end of the following growing season for that crop in the area.

5. BBEP should be notified of any proposed changes to the protocol referenced in the permit application.

6. This approved Biotechnology Permit (APHIS form #2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (1) for the use of any non-genetically engineered plant pest or pathogens as challenge inoculum; (2) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (3) experimental use of unregistered chemical; and (4) food or feed use of genetically engineered crops harvested from the field experiment.

OR120018_BR_011812

Standard Permit Conditions
For the Introduction of a
Regulated Article
(7 CFR 340.3(f))

Permit Conditions: A person who is issued a permit and his/her employees or agents shall comply with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Deputy Administrator to be necessary to prevent the dissemination and establishment of plant pests:

(1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests.

(2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of plant pests.

(3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit.

(4) The regulated article shall be maintained only in areas and premises specified in the permit.

(5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article.

(6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation.

(7) The regulated article shall be subject to the application of measures determined by the Deputy Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article.

(8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the Deputy Administrator to be necessary to prevent spread of plant pests.

(9) A person who has been issued a permit shall submit to Biotechnology, Biologics, and Environmental Protection monitoring reports on the performance characteristics of the regulated article, in accordance with any monitoring reporting requirements that may be specified in a permit.

(10) Biotechnology, Biologics, and Environmental Protection shall be notified within the time periods and manner specified below, in the event of the following occurrences:

(i) Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article;

(ii) In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms);

(11) A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:

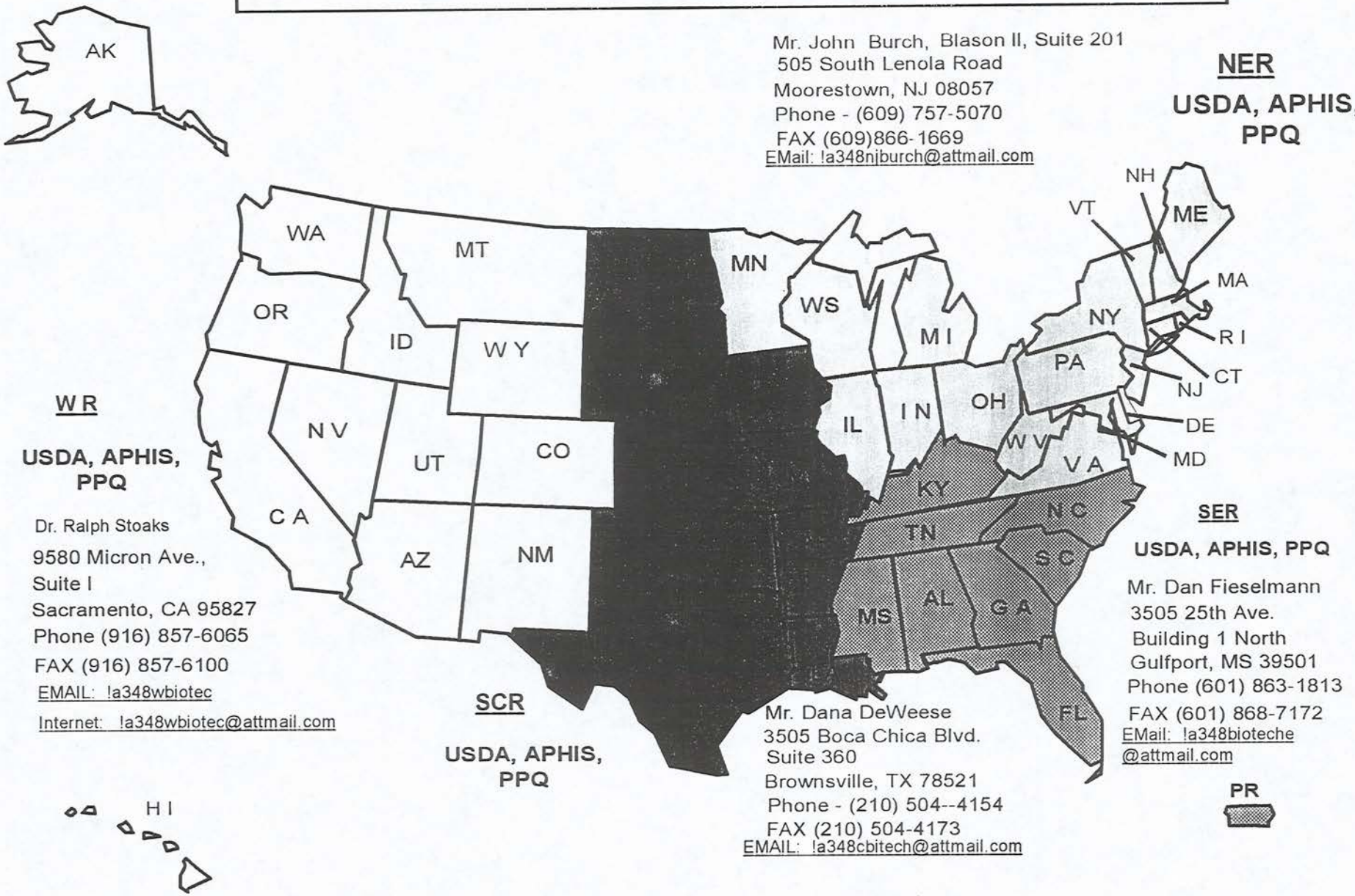
(i) Import or offer the regulated article for entry only at a port of entry which is designated by an asterisk in 7 CFR 319.37-14(b);

(ii) Notify Biotechnology, Biologics, and Environmental Protection promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

(iii) Mark and identify the regulated article in accordance with 7 CFR 340.5.

OR120018_BR_011813

PLANT PROTECTION AND QUARANTINE
Regional Contacts - (Biotechnology Activities)



NER

USDA, APHIS, PPQ

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505 South Lenola Road
Moorestown, NJ 08057
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WR

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SER

USDA, APHIS, PPQ

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EMail: !a348bioteche
@attmail.com

OR120018_BR_011814

This application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq. and the Plant Quarantine Act (7 U.S.C. 151 et seq.)). The information will be used to determine eligibility to receive all types of permits. No permit shall be issued until this application has been approved

See reverse side for additional information

FORM APPROVED OMB NO. 0579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

(Genetically Engineered Organisms or Products) 96-008PR

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

1. NAME AND ADDRESS OF APPLICANT

(b) (6), (b) (7)(C)
Monsanto Agricultural Group
700 Chesterfield Parkway North BB3A
Area Code Chesterfield, MO 63198

2. PERMIT REQUESTED ("X" one)

- [ ] Limited - Interstate Movement
- [ ] Limited - Importation
- [XX] Release into the Environment
- [ ] Courtesy Permit

3. THIS REQUEST IS ("X" one)

- [XX] New
- [ ] Renewal
- [ ] Supplemental

4. TELEPHONE NUMBER

96-019-03r

(b) (6), (b) (7)(C)

5. MEANS OF MOVEMENT

- [ ] Mail
- [ ] Baggage or Handcarried
- [X] Common Carrier
- By whom _____

6. GIVE THE FOLLOWING *(if applicable) (if more space is needed, attach additional sheet)*

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism:				
b. Recipient Organism:	SEE ATTACHED			
c. Vector or Vector Agent:				
d. Regulated Organism or Product:				
e. If product, list names of constituents:				

7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS

SEE ATTACHED

8. DATE *(or inclusive dates of period)* **OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE**

SEE ATTACHED

9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

SEE ATTACHED

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

SEE ATTACHED

11. ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* **ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT**

NONE

93-165

12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

NOT APPLICABLE

13. SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON	15. PRINTED NAME AND TITLE	16. DATE
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	1/17/96

FOR APHIS USE ONLY

State Notification Sent	State Review Received	Permit Issued
January 31, 1996	WA = 2/16/96, MN = 4/22/96	[XX] Yes [ ] No

Date of Determination	Permit No.	No. of Permit Labels Issued	Supplemental Conditions Enclosed
April 23, 1996	96-019-03r	n/a	[XX] Yes [ ] No

Signature of BBEP Official	Date	Expiration Date
Arnold Foudin, Deputy Director, BP	April 23, 1996	April 23, 1997

APHIS FORM 2000 (JUL 89) *Replaces PPQ Form 1001 which may be used.*

OR120018_BR_011815

(continued on reverse)

	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a.	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article	X	
b.	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics)	X	
c.	A detailed description of the molecular biology of the system (e g , donor-recipient-vector) which is or will be used to produce the regulated article	X	
d.	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced	X	
e.	A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design.	X	
f.	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product, and, regulated article.	X	
g.	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location, production, propagation, and manufacture location; proposed sale and distribution location).	X	
h.	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.	X	
i.	A detailed description of the proposed method of final disposition of the regulated article	X	

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

OR120018_BR_011816

Notice

Confidential Business Information

Some information in the attached material may be entitled to treatment as trade secret or proprietary data under Section(b)(4) of the Freedom of Information Act (FOIA) [5 U.S.C. 552(b)(4)].

Any person handling or using the attached data in any way is responsible for preventing unauthorized disclosure during possession.

Maintain this document under secure conditions.

Return to the Document Control Officer after use.

This application deals with:

MONSANTO - Widestrike - HT - Stacked - NP/NA

Identification Number:

96-019-03R

The attached information is not to be published, reproduced, publicly discussed, included in response to a FOIA request, or otherwise released without the explicit written authorization of the appropriate division director or designee.

Please disqualify yourself if there is any potential Conflict of Interest

OR120018_BR_011817

Monsanto

96-019-03R

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

January 17, 1996

Ms. E. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology, Biologics, and Environmental Protection
Biotechnology Permits
4700 River Road, Unit 147
Riverdale, MD 20737-1237

Subject: Request for a Permit to Field Test a Disease Protection Gene in Wheat
Monsanto # 96-008PR

Dear Ms. Hatmaker:

Monsanto Agricultural Company is requesting a permit from USDA to allow wheat which has been genetically modified for tolerance to glyphosate herbicide to be tested in North Dakota and Washington.

In support of this request for a permit to allow release into the environment, please find the completed APHIS Form 2000 attached to this letter. In addition we are submitting 1 copy of the application containing the required information to support this request. This volume contains confidential business information (CBI) and is so marked on the cover and each place within the volume where the CBI occurs. As required, we are also submitting 1 copy of this same material with all CBI deleted. The vectors associated with this release was previously approved for use in field trials or interstate movements under USDA permits #94-221-01, 95-010-01 and 95-039-07M.

This confidential information was developed by Monsanto at its own expense, has not been released to anyone not under a secrecy agreement to Monsanto and has not been published. We request that this information not be released as it has value to our competitors (domestic and foreign) in that they would be able to copy this work and unfairly compete with us causing financial loss and other harm to Monsanto.

We appreciate your attention to this matter. Should you have any questions, please feel free to contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

CONTAINS CBI

OR120018_BR_011818

This application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq. and the Plant Quarantine Act (7 U.S.C. 151 et seq.)). The information will be used to determine eligibility to receive all types of permits. No permit shall be issued until this application has been approved.

See reverse side for additional information.

FORM APPROVED
OMB NO. 0579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

(Genetically Engineered Organisms or Products) 96-008PR

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

1. NAME AND ADDRESS OF APPLICANT

(b) (6), (b) (7)(C)
Monsanto Agricultural Group
700 Chesterfield Parkway North BB3A
Chesterfield, MO 63198

Area Code ( )

2. PERMIT REQUESTED ("X" one)

- [ ] Limited - Interstate Movement
- [ ] Limited - Importation
- [XX] Release into the Environment
- [ ] Courtesy Permit

3. THIS REQUEST IS *("X" one)*

- [XX] New
- [ ] Renewal
- [ ] Supplemental

4. TELEPHONE NUMBER

(b) (6), (b) (7)(C)

5. MEANS OF MOVEMENT

- [ ] Mail
- [ ] Baggage or Handcarried
- [X] Common Carrier — By whom _____

6. GIVE THE FOLLOWING *(if applicable) (if more space is needed, attach additional sheet)*

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism:				
b. Recipient Organism:	SEE ATTACHED			
c. Vector or Vector Agent:				
d. Regulated Organism or Product:				
e. If product, list names of constituents:				

7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS

SEE ATTACHED

8. DATE *(or inclusive dates of period)* OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE

SEE ATTACHED

9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

SEE ATTACHED

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

SEE ATTACHED

11. ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT

NONE

12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

NOT APPLICABLE

13. SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON	15. PRINTED NAME AND TITLE	16. DATE
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	1/17/96

FOR APHIS USE ONLY

State Notification Sent	State Review Received	Permit Issued [ ] Yes [ ] No
Date of Determination	Permit No.	No. of Permit Labels Issued
		Supplemental Conditions Enclosed [ ] Yes [ ] No
Signature of BBEP Official	Date	Expiration Date

APHIS FORM 2000 (JUL 89) *Replaces PPQ Form 1001 which may be used.*

OR120018_BR_011819

(continued on reverse)

	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a.	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article	X	
b.	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics)	X	
c.	A detailed description of the molecular biology of the system (e g . donor-recipient-vector) which is or will be used to produce the regulated article.	X	
d.	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced.	X	
e.	A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design.	X	
f.	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product, and, regulated article.	X	
g.	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location; production, propagation, and manufacture location; proposed sale and distribution location).	X	
h.	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.	X	
i.	A detailed description of the proposed method of final disposition of the regulated article	X	

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

OR120018_BR_011820

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (lOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been

substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.[1]

[1] In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011822

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of marker genes in plants and their use in insect and virus resistant and herbicide tolerant crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Calgene, Rhone-Poulenc, Zeneca, and Ciba.

OR120018_BR_011823

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

OR120018_BR_011824

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for wheat has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

OR120018_BR_011825

Attachment
Confidential Business Information Justification
Disease Gene in Wheat

Page	Category of Information	Justification
1	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
1	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
2	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
2	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
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3	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms

OR120018_BR_011826

3	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
7	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

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9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

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11	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

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12	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
13	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
13	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
13	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011830

APHIS FORM 2000 ATTACHMENTS

This request for a Release in to the Environment Permit is to allow the field testing of genes for herbicide tolerance in genetically modified wheat at the locations specified in item 10. All of the information required to support this permit is found in this application.

The vectors that will be tested in this field trial are: PV-TXCT01. PV-TXCT15, PV-TXCT21, PV-TXCT23 and PV-TXCT28.

Item 5. Means of Movement

The wheat seeds will be shipped via common carrier.

Item 6. Information on the Donor, Recipient, Method of Transformation and Regulated Article.

a. For Construct PV-TXCT01 - (PV-TXGT01 + PV-TXSM01)

Plasmid Vector PV-TXGT01:

	Scientific Name	Common Name
CBI a. Donor Organism	[redacted] (b) (4) *Arabidopsis thaliana* *Agrobacterium sp.* strain CP4 *Achromobacter* sp. strain LBAA	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector or Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid Vector PV-TXSM01:

	Scientific Name	Common Name
CBI a. Donor Organism	[redacted] (b) (4) *Escherichia coli*	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

OR120018_BR_011831

b. For Construct PV-TXCT15 - (PV-TXFR05 + PV-TXSM09)

Plasmid Vector PV-TXFR05:

	Scientific Name	Common Name
CBI a. Donor Organism	(b) (4)	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid Vector PV-TXSM09:

	Scientific Name	Common Name
CBIa. Donor Organism CBI	(b) (4)	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

c. For Construct PV-TXCT21 - (PV-TXSM09 + PV-TXSM11)

Plasmid Vector PV-TXSM09:

See Description Above

Plasmid Vector PV-TXSM11:

	Scientific Name	Common Name
CBI a. Donor Organism CBI	(b) (4)	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

OR120018_BR_011832

d. For Construct PV-TXCT23 - (PV-TXSM09 + PV-TXSM12)

Plasmid Vector PV-TXSM09:

See Description Above

Plasmid Vector PV-TXSM12:

		Scientific Name	Common Name
CBI	a. Donor Organism	(b) (4)	
CBI			
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

e. For Construct PV-TXCT28 - (PV-TXFR02 + PV-TXSM09)

Plasmid vector PV-TXFR02:

		Scientific Name	Common Name
CBI	a. Donor Organism	(b) (4)	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid Vector PV-TXSM09

See Description Above

Item 7: Quantity of Regulated Article to be Introduced and Proposed Schedule of Introduction.

Up to 50 separate lines of the wheat transformed with vectors will be planted in a randomized block design. There will be 2 to 3 replicates depending on seed quantity. Therefore the total area to be planted to the transgenic wheat plants will be up to 2.0 acres at each location.

OR120018_BR_011833

Item 8: Date of Release

- Planting: April 1 to May 31, 1996 depending on weather and seed availability.
- Harvest: The experiment will be harvested between August and October of 1996, depending on weather and date of planting.

Item 9: Country of Point of Origin of the Regulated Article.

The donor, recipient and vector organisms were collected in the United States. The vector construct and transgenic wheat were developed by Monsanto at the (b) (4) The planting material will be wheat seeds produced by and shipped from:

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) Missouri (b) (4), (b) (6), (b) (7)(C)
Tel.: (b) (4), (b) (6), (b) (7)(C)
Fax.: (b) (4), (b) (6), (b) (7)(C)

Item 10. Port of Arrival, Destination of Movement, or Specific Location of Release

Moorhead, Minnesota

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C)
Tel: (b) (4), (b) (6), (b) (7)(C)

Location of Experiment

(b) (4), (b) (6), (b) (7)(C)

Walla Walla, Washington

(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C)
Tel/FAX: (b) (4), (b) (6), (b) (7)(C)

OR120018_BR_011834

Location of Experiment

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C)

Item 13a. Names, Addresses and Telephone Numbers of the Persons Who Developed and/or Supplied the Regulated Article.

The plasmid vectors and transformed wheat plants were developed by scientists at Ceregen, a unit of Monsanto, at Monsanto's research facility located in Chesterfield, Missouri. For additional information contact the applicant of this permit.

Item 13b. A Description of the Expression of the Regulated Article:

It is anticipated that the transgenic wheat plants will have tolerance to Roundup® herbicide.

The transgenic material that is the recipient of the added genes is the CIMMYT(Centro Internaclonal de Mejoramiento de Maiz y Trigo, Facimile 52-595-41069) line Bobwhite. The line Bobwhite was designated to a group of advanced lines derived from the cross Aurora/Kalyan/Bluebird/3/Woodpecker CM33203. This cross was made at CIMMYT in 1973.

Bobwhite is a general semidwarf wheat and carries resistance to septoria tritici, leaf rust, and the gene YR9 for stripe rust. The Bobwhite lines carry the 1B/1R translocation i.e. 1BS is translocated by 1RS of rye. The 1B/1R was derived from the variety Aurora from the USSR. Despite the fact that it carries 1B/1R translocation associated with poor quality(stickiness), industrial quality of Bobwhite is good, and acceptable in most countries.

The Bobwhite line has been genetically -modified by particle bombardment for co-transformation of one of the scorable or selectable markers described . At present no molecular or segregation data is available from the lines that will be evaluated in the field trial. However the original transformed plants have been qualitatively evaluated for gene expression of the selectable marker/s with positive results.

Tolerance to glyphosate herbicide was accomplished through a "target-site" approach, whereby a herbicide-insensitive target protein was identified and introduced into wheat by genetic modification techniques. Glyphosate specifically binds to and blocks the activity of its enzyme target, 5-enolpyruvylshikimate-3-phosphate synthase (EPSP synthase, EPSPS), an enzyme of the aromatic amino acid biosynthetic pathway.

OR120018_BR_011835

Glyphosate inhibition of EPSPS thus prevents the plant from synthesizing the aromatic amino acids essential for protein synthesis. EPSPS is the only physiological target of glyphosate in plants, and no other phosphoenolpyruvate (PEP)-utilizing enzymes are inhibited by glyphosate. EPSPS is present in all plants, bacteria, and fungi, but not animals; animals do not make their own aromatic amino acids, but receive them from plant, microbial, or animal foods. In plants, EPSPS is localized in the chloroplasts or plastids. Upon glyphosate treatment, the GTS plant remains unaffected because the continued action of the introduced glyphosate-tolerant EPSPS enzyme meets the plant's need for aromatic amino acids. This is in contrast to the death or severe yield reduction observed upon glyphosate treatment of non-glyphosate-tolerant plants.

Extensive research indicated that a crucial factor for obtaining high levels of glyphosate tolerance *in planta* depended on the expression of a glyphosate-tolerant EPSPS with a high catalytic efficiency in the presence of glyphosate. The EPSPS enzyme from *Agrobacterium* sp. strain CP4 (CP4 EPSPS) was identified from a screen of microorganism cell extracts as having very favorable glyphosate tolerance kinetic parameters, namely high glyphosate tolerance and tight binding of PEP Based on these kinetic parameters, and thus the suitability for use in conferring glyphosate tolerance to crops, the gene for CP4 EPSPS was cloned from *Agrobacterium* sp. strain CP4, and inserted into the wheat plants to confer tolerance to glyphosate herbicide.

Item 13c. The Description of the Plasmid Vector as Inserted Into these Wheat Plants is Described Below.

Construct Description for PV-TXCT01

PV-TXGT01 AND TXSM01 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXGT01

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

OR120018_BR_011836

CBI **CMoVa/**(b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI (b) (4)

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.
CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature CP4 protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI **CMoVa/**(b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI (b) (4)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.
CTP1-GMEsyn is a gene fusion composed of the N-terminal 0.26 Kb chloroplast transit peptide sequence derived from the *Arabidopsis thaliana* SSU 1a gene (CTP1) (Timko et al. 1988, The Impact of Chemistry on Biotechnology, ACS Books, 279-295), and the C-terminal 1.3 Kb synthetic gene sequence (GMEsyn). GMEsyn gene encodes the enzyme glyphosate oxidoreductase from an *Achromobacter* sp. strain LBAA which catalyzes the conversion of glyphosate to herbicidally inactive products, aminomethylphosphonate and glyoxylate. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature GMEsyn protein.

OR120018_BR_011837

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

Construct Description for PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[redacted] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al. 1987, Science 236:1299-1302)

CBI [redacted]

GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXCT15

PV-TXFR05 AND PV-TXSM09 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

OR120018_BR_011838

Construct Description for PV-TXFR05

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CBI **CMP1**[(b) (4)] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [(b) (4)]

Antifungal Protein Gene II Expression of AFP2 confers resistance to fungal diseases.

CBI [(b) (4)]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

Construct Description for PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[(b) (4)] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [(b) (4)]

OR120018_BR_011839

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.

CBI [redacted]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXCT21

PV-TXSM09 AND PV-TXSM11 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXSM09

See Description Above

Construct Description for PV-TXSM11

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **TSP2/**[redacted] The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.

CBI [redacted]

OR120018_BR_011840

AS1 Expression of this sequence alters the expression of marker genes.

CBI [redacted]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI **TSP2/**[redacted] The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.

CBI [redacted]

TMG1 The expression of this gene is used as a marker for plant transformation.

CBI [redacted]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXCT23

PV-TXSM09 AND PV-TXSM12 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXSM09

See Description Above

OR120018_BR_011841

Construct Description for PV-TXSM12

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **TSP3/**(b) (4) The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

CBI [redacted]

AS1 Expression of this sequence alters the expression of marker genes.

CBI [redacted]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI **TSP3/**(b) (4) The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

CBI [redacted]

TMG1 The expression of this gene is used as a marker for plant transformation.

CBI [redacted]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011842

CONSTRUCT DESCRIPTION FOR PV-TXCT28

PV-TXFR02 AND PV-TXSM09 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXFR02

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CBI **CMoVa/I**[redacted] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al. 1987, Science 236:1299-1302).

CBI [redacted]

Antifungal Protein Gene II Expression of AFP2 confers resistance to fungal diseases.

CBI [redacted]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

Construct Description for PV-TXSM09

See Description Above

OR120018_BR_011843

FREE DELIVERY PARTICLE GUN (MONSANTO)

Introduction of DNA into plant tissue with the "biolistic" particle bombardment method has been described in detail by Klein et al. (1987, Nature 327: 70-73; 1988a, Bio/Technology 6: 559-563; and 1988b, Proc Natl Acad Sci USA 85: 4305-4309). The transgenic material in this application was produced using the commercially available particle delivery systems. Detailed instructions are available from the manufacturers. Briefly, DNA is precipitated onto microscopic (~1 μ diameter) tungsten or gold particles using calcium chloride and spermidine. A drop (2.5μl) of the coated particles is accelerated at a high velocity allowing the particles to penetrate the target plant cells, where the DNA is deposited and incorporated into the plant cell genome. The cells are incubated on a tissue culture medium which supports the growth of embryogenic callus. The introduced DNA contains a gene(s) encoding for resistance to either antibiotics (e.g., the NPTII gene for resistance to kanamycin and G418) or genes conferring herbicide resistance. The plant cells are grown in the presence of an appropriate antibiotic or herbicide, and only the transformed cells continue to grow. Plants are regenerated from the resistant embryogenic callus tissue, and are assayed for the presence of the introduced gene(s). The free delivery vectors are engineered to contain multiple chimeric plant expression genes in high copy E. coli plasmids.

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Kan

The free delivery vectors contain multiple chimeric plant expression genes engineered into pMON10081. The pMON10081 plasmid is a derivative of the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). It was constructed by fusing the 1.3 Kb FspI-DraI origin of replication fragment from pUC119, to the 1.3 Kb SmaI-HindIII (Klenow filled) fragment from pKC7 (Rao and Rogers 1979, Gene 7: 79). The pKC7 fragment contains the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance. The ß-lactamase gene conferring bacterial ampicillin resistance was completely deleted. Several chimeric plant expression genes can be introduced into pMON10081. These include the marker genes required for selection of the transformed plant tissue, and one or more chimeric genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

Item 13d. The plasmid vectors were constructed at the research laboratories of Monsanto Co. in St. Louis, Missouri. The initial wheat plants transformed with these vectors were also developed at the research laboratories of Monsanto Co. in St. Louis, Missouri, USA.

OR120018_BR_011844

Item 13e. A Detailed Description of the Purpose for the Regulated Article.

PROPOSED EXPERIMENTAL PROGRAM

Expt AGW96-1

Purpose of the test:

To evaluate the tolerance to Roundup herbicide of the transgenic lines under field conditions.

To evaluate agronomic performance, yield and yield components of the lines.

Investigators:

Principle Investigator:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) Missouri (b) (4), (b) (6), (b) (7)(C)
Tel.: (b) (4), (b) (6), (b) (7)(C)
Fax.: (b) (4), (b) (6), (b) (7)(C)

Site Investigators:

(b) (4), (b) (6), (b) (7)(C) North Dakota

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) ND (b) (4), (b) (6), (b) (7)(C)
Tel: (b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) Washington

Principle Researcher:

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C)
Tel/FAX: (b) (4), (b) (6), (b) (7)(C)

Location of Experiment

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) WA (b) (4), (b) (6), (b) (7)(C)

OR120018_BR_011845

(b) (4), (b) (6), (b) (7)(C)

Site Description:

- (b) (4), (b) (6), (b) (7)(C) **Minnesota**

(b) (4), (b) (6), (b) (7)(C)

- (b) (4), (b) (6), (b) (7)(C) **Washington**

(b) (4), (b) (6), (b) (7)(C)

Field Test Design:

- Each plot will consist of one to four rows, 4-12 inches apart and up to 20 feet long.
- The trial will be established using a randomized complete block design.
- The number of replications will be determined by seed availability, however, it is anticipated that the experiment will have either 2 or 3 replications.

Genotypes:

- Up to 50 lines of homozygous and segregating progeny of lines transformed with plasmid vectors PV-TXSM09, PV-TXSM01 and PV-TXGT01.
- Non-transgenic Bobwhite and other control lines.

OR120018_BR_011846

Space requirements:

- The transgenic material will cover no more than 2.0 acres.
- The total area needed for the entire test will be no greater than 3.0 acres.

Isolation:

- The experiment will be surrounded by a 20 foot border of wheat to prevent outcrossing to wheat and other species not a part of this trial.

Tentative schedule:

- Planting: April 1 to May 31, 1996 depending on weather and seed availability.
- Harvest: The experiment will be harvested between August and October of 1996, depending on weather and date of planting.

Agronomic practices:

- Ground preparation and fertility: Ground preparation will follow normal practices for wheat. Fertilizer may be applied based on a soil test to bring the nutrient level up to that recommended for wheat. Additional fertilizer may be applied throughout the season as needed.
- Weed control: Weed control will follow acceptable practices for wheat by using labelled herbicides, experimental herbicides, and/or hand weeding.
- Disease control: Diseases may be controlled by the use of labelled fungicides for seed treatment and/or topical applications.
- Insect control: Insect pests will be monitored for their appearance in the field. Insecticides labelled to control insect pests that are present may be applied as needed, including seed treatments or topical applications.

Treatment

- The wheat will be treated with a 16 or 32 ounce per acre treatment of Roundup herbicide at either the 3rd or 6th leaf stage of growth.

Sampling:

- Leaf and other tissue samples may be taken from the plots and analyzed for disease infection and expression of the inserted trait. Such analyses will be conducted at Monsanto's research facility in Chesterfield, Missouri. A separate Limited Interstate movement permit will be applied for to cover these planned movements.

OR120018_BR_011847

Data Collection

- Roundup herbicide tolerance

  Evaluate the levels of chlorosis, necrosis and growth reduction 14 and 28 days after spraying.

  Evaluate the color and size of the anthers

  Measure the percent fertility of the treated plants.

- Agronomic traits

  The following will be recorded or evaluated; heading date, plant height, shattering and disease susceptibility

- Yield will be taken from all plots which produce grain.

Harvest procedures:

- The plots will either be harvested by hand or with a small plot combine. If the combine is used, it will be thoroughly cleaned following completion of the plot harvesting and before leaving the plot area.

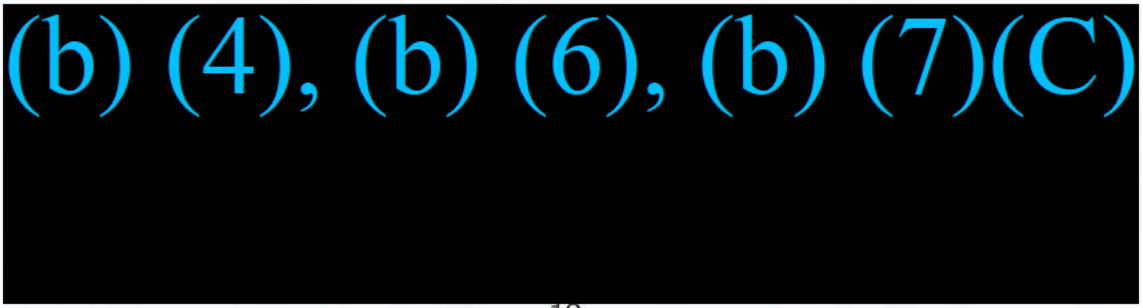
Plant and seed disposal:

- After harvest, the test plot will be tilled to destroy the plant material. After tillage the plot area will be monitored for 1 year for surviving plants, which will be destroyed by hand, tillage or herbicide treatment. Wheat or another small grain will not be planted in this area for one year.

Item 13f. All research and procedures used in the production of the donor organism, recipient organism, vector or vector agent and the transgenic wheat were done utilizing level BL2 containment according to the NIH Guidelines for Recombinant DNA Research.

Item 13g. A Detailed Description of the Intended Destination

- (b) (4), (b) (6), (b) (7)(C) **Minnesota**



OR120018_BR_011848

- (b) (4), (b) (6), (b) (7)(C) Washington

(b) (4), (b) (6), (b) (7)(C)

Item 13h. Procedures, Processes and Safeguards that Will be Used to Prevent Escape and Dissemination of the Regulated Article.

The wheat seeds will be shipped to and from the field sites in compliance with 7 CFR 340.5 and 340.6 in containers fastened to preclude spillage. Movement will be by common carrier or air freight. The wheat seeds will be placed in secure storage with restricted access at the field sites prior to planting. None of the wheat seed or plant material produced in this experiment will enter commerce or will be consumed by domestic animals. Any plant tissue returned from the field site will be frozen and therefore not viable.

This trial will be clearly marked and separated from other wheat which may be growing in the vicinity. Such marking and isolation will prevent the accidental mixing of with conventional wheat varieties. The test will be terminated prior to harvest. After sampling, the test plot will be tilled or cut to destroy the plant material.

Item 13i. Proposed Method of Final Disposition of the Regulated Article

After harvest, the test plot will be tilled to destroy the plant material. The plot area will be monitored for one year following harvest, and any surviving plants will be destroyed by hand, tillage or herbicide treatment.

OR120018_BR_011849

Monsanto

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

January 17, 1996

Ms. E. Dianne Hatmaker
Animal and Plant Health Inspection Services
Biotechnology, Biologics, and Environmental Protection
Biotechnology Permits
4700 River Road, Unit 147
Riverdale, MD 20737-1237

Subject: Request for a Permit to Field Test a Disease Protection Gene in Wheat
Monsanto # 96-008PR

Dear Ms. Hatmaker:

Monsanto Agricultural Company is requesting a permit from USDA to allow wheat which has been genetically modified for tolerance to glyphosate herbicide to be tested in North Dakota and Washington.

In support of this request for a permit to allow release into the environment, please find the completed APHIS Form 2000 attached to this letter. In addition we are submitting 1 copy of the application containing the required information to support this request. This volume contains confidential business information (CBI) and is so marked on the cover and each place within the volume where the CBI occurs. As required, we are also submitting 1 copy of this same material with all CBI deleted. The vectors associated with this release was previously approved for use in field trials or interstate movements under USDA permits #94-221-01, 95-010-01 and 95-039-07M.

This confidential information was developed by Monsanto at its own expense, has not been released to anyone not under a secrecy agreement to Monsanto and has not been published. We request that this information not be released as it has value to our competitors (domestic and foreign) in that they would be able to copy this work and unfairly compete with us causing financial loss and other harm to Monsanto.

We appreciate your attention to this matter. Should you have any questions, please feel free to contact me at (b) (6), (b) (7)(C)

Sincerely,

(b) (6), (b) (7)(C)

CBI DELETED

OR120018-BR-011850

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (lOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been

substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F.Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.[1]

[1] In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011852

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of marker genes in plants and their use in insect and virus resistant and herbicide tolerant crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Calgene, Rhone-Poulenc, Zeneca, and Ciba.

OR120018_BR_011853

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

OR120018_BR_011854

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for wheat has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

OR120018_BR_011855

Attachment
Confidential Business Information Justification
Disease Gene in Wheat

Page	Category of Information	Justification
1	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
1	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
2	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
2	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
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3	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
3	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms

OR120018_BR_011856

3	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
7	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011857

9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
9	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011858

11	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011859

12	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
13	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
13	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
13	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011860

APHIS FORM 2000 ATTACHMENTS

This request for a Release in to the Environment Permit is to allow the field testing of genes for herbicide tolerance in genetically modified wheat at the locations specified in item 10. All of the information required to support this permit is found in this application.

The vectors that will be tested in this field trial are: PV-TXCT01. PV-TXCT15, PV-TXCT21, PV-TXCT23 and PV-TXCT28.

Item 5. Means of Movement

The wheat seeds will be shipped via common carrier.

Item 6. Information on the Donor, Recipient, Method of Transformation and Regulated Article.

a. For Construct PV-TXCT01 - (PV-TXGT01 + PV-TXSM01)

Plasmid Vector PV-TXGT01:

		Scientific Name	Common Name
CBI	a. Donor Organism	[*Arabidopsis thaliana* *Agrobacterium sp.* strain CP4 *Achromobacter* sp. strain LBAA] CBI DELETED	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector or Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid Vector PV-TXSM01:

		Scientific Name	Common Name
CBI	a. Donor Organism	[*Escherichia coli*] CBI DELETED	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

OR120018_BR_011861

b. For Construct PV-TXCT15 - (PV-TXFR05 + PV-TXSM09)

Plasmid Vector PV-TXFR05:

	Scientific Name	Common Name
CBI a. Donor Organism	[	] CBI DELETED
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid Vector PV-TXSM09:

	Scientific Name	Common Name
CBIa. Donor Organism	[	] CBI DELETED
CBI	[	]
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

c. For Construct PV-TXCT21 - (PV-TXSM09 + PV-TXSM11)

Plasmid Vector PV-TXSM09:

See Description Above

Plasmid Vector PV-TXSM11:

	Scientific Name	Common Name
CBI a. Donor Organism	[	] CBI DELETED
CBI	[ ]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

OR120018_BR_011862

d. For Construct PV-TXCT23 - (PV-TXSM09 + PV-TXSM12)

Plasmid Vector PV-TXSM09:

See Description Above

Plasmid Vector PV-TXSM12:

		Scientific Name	Common Name
CBI	a. Donor Organism	[	] CBI DELETED
CBI		[ ]	
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

e. For Construct PV-TXCT28 - (PV-TXFR02 + PV-TXSM09)

Plasmid vector PV-TXFR02:

		Scientific Name	Common Name
CBI	a. Donor Organism	[	] CBI DELETED
	b. Recipient Organism	*Triticum aestivum*	wheat
	c. Vector of Vector Agent	particle gun	
	d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid Vector PV-TXSM09

See Description Above

Item 7: Quantity of Regulated Article to be Introduced and Proposed Schedule of Introduction.

Up to 50 separate lines of the wheat transformed with vectors will be planted in a randomized block design. There will be 2 to 3 replicates depending on seed quantity. Therefore the total area to be planted to the transgenic wheat plants will be up to 2.0 acres at each location.

OR120018_BR_011863

Item 8: Date of Release

- Planting: April 1 to May 31, 1996 depending on weather and seed availability.
- Harvest: The experiment will be harvested between August and October of 1996, depending on weather and date of planting.

Item 9: Country of Point of Origin of the Regulated Article.

The donor, recipient and vector organisms were collected in the United States. The vector construct and transgenic wheat were developed by Monsanto at the (b) (6), (b) (7)(C), (b) (4) The planting material will be wheat seeds produced by and shipped from:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Missouri (b) (6), (b) (7)(C), (b) (4)
Tel.: (b) (6), (b) (7)(C), (b) (4)
Fax.:

Item 10. Port of Arrival, Destination of Movement, or Specific Location of Release

Moorhead, Minnesota

Principle Researcher

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) ND (b) (6), (b) (7)(C), (b) (4)
Tel: (b) (6), (b) (7)(C), (b) (4)

Location of Experiment

(b) (6), (b) (7)(C), (b) (4)

Walla Walla, Washington

Principle Researcher:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) WA (b) (6), (b) (7)(C), (b) (4)
Tel/FAX: (b) (6), (b) (7)(C), (b) (4)

OR120018_BR_011864

Location of Experiment

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) WA (b) (6), (b) (7)(C), (b) (4)

Item 13a. Names, Addresses and Telephone Numbers of the Persons Who Developed and/or Supplied the Regulated Article.

The plasmid vectors and transformed wheat plants were developed by scientists at Ceregen, a unit of Monsanto, at Monsanto's research facility located in Chesterfield, Missouri. For additional information contact the applicant of this permit.

Item 13b. A Description of the Expression of the Regulated Article:

It is anticipated that the transgenic wheat plants will have tolerance to Roundup® herbicide.

The transgenic material that is the recipient of the added genes is the CIMMYT(Centro Internaclonal de Mejoramiento de Maiz y Trigo, Facimile 52-595-41069) line Bobwhite. The line Bobwhite was designated to a group of advanced lines derived from the cross Aurora/Kalyan/Bluebird/3/Woodpecker CM33203. This cross was made at CIMMYT in 1973.

Bobwhite is a general semidwarf wheat and carries resistance to septoria tritici, leaf rust, and the gene YR9 for stripe rust. The Bobwhite lines carry the 1B/1R translocation i.e. 1BS is translocated by 1RS of rye. The 1B/1R was derived from the variety Aurora from the USSR. Despite the fact that it carries 1B/1R translocation associated with poor quality(stickiness), industrial quality of Bobwhite is good, and acceptable in most countries.

The Bobwhite line has been genetically -modified by particle bombardment for co-transformation of one of the scorable or selectable markers described . At present no molecular or segregation data is available from the lines that will be evaluated in the field trial. However the original transformed plants have been qualitatively evaluated for gene expression of the selectable marker/s with positive results.

Tolerance to glyphosate herbicide was accomplished through a "target-site" approach, whereby a herbicide-insensitive target protein was identified and introduced into wheat by genetic modification techniques. Glyphosate specifically binds to and blocks the activity of its enzyme target, 5-enolpyruvylshikimate-3-phosphate synthase (EPSP synthase, EPSPS), an enzyme of the aromatic amino acid biosynthetic pathway.

OR120018_BR_011865

Glyphosate inhibition of EPSPS thus prevents the plant from synthesizing the aromatic amino acids essential for protein synthesis. EPSPS is the only physiological target of glyphosate in plants, and no other phosphoenolpyruvate (PEP)-utilizing enzymes are inhibited by glyphosate. EPSPS is present in all plants, bacteria, and fungi, but not animals; animals do not make their own aromatic amino acids, but receive them from plant, microbial, or animal foods. In plants, EPSPS is localized in the chloroplasts or plastids. Upon glyphosate treatment, the GTS plant remains unaffected because the continued action of the introduced glyphosate-tolerant EPSPS enzyme meets the plant's need for aromatic amino acids. This is in contrast to the death or severe yield reduction observed upon glyphosate treatment of non-glyphosate-tolerant plants.

Extensive research indicated that a crucial factor for obtaining high levels of glyphosate tolerance *in planta* depended on the expression of a glyphosate-tolerant EPSPS with a high catalytic efficiency in the presence of glyphosate. The EPSPS enzyme from *Agrobacterium* sp. strain CP4 (CP4 EPSPS) was identified from a screen of microorganism cell extracts as having very favorable glyphosate tolerance kinetic parameters, namely high glyphosate tolerance and tight binding of PEP Based on these kinetic parameters, and thus the suitability for use in conferring glyphosate tolerance to crops, the gene for CP4 EPSPS was cloned from *Agrobacterium* sp. strain CP4, and inserted into the wheat plants to confer tolerance to glyphosate herbicide.

Item 13c. The Description of the Plasmid Vector as Inserted Into these Wheat Plants is Described Below.

Construct Description for PV-TXCT01

PV-TXGT01 AND TXSM01 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXGT01

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

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CBI DELETED

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
[

CBI DELETED

]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants.
CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature CP4 protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI DELETED

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
[

CBI DELETED

]

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.
CTP1-GMEsyn is a gene fusion composed of the N-terminal 0.26 Kb chloroplast transit peptide sequence derived from the *Arabidopsis thaliana* SSU 1a gene (CTP1) (Timko et al. 1988, The Impact of Chemistry on Biotechnology, ACS Books, 279-295), and the C-terminal 1.3 Kb synthetic gene sequence (GMEsyn). GMEsyn gene encodes the enzyme glyphosate oxidoreductase from an *Achromobacter* sp. strain LBAA which catalyzes the conversion of glyphosate to herbicidally inactive products, aminomethylphosphonate and glyoxylate. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature GMEsyn protein.

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NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

Construct Description for PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI DELETED

CMoVa/[ ] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

[

CBI DELETED

]

GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXCT15

PV-TXFR05 AND PV-TXSM09 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

OR120018_BR_011868

Construct Description for PV-TXFR05

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CMP1/[CBI DELETED **]** The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.
[CBI DELETED]

Antifungal Protein Gene II Expression of AFP2 confers resistance to fungal diseases.
[CBI DELETED]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

Construct Description for PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/[CBI DELETED **]** A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
[CBI DELETED]

OR120018_BR_011869

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants.
[

CBI
DELETED

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXCT21

PV-TXSM09 AND PV-TXSM11 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXSM09

See Description Above

Construct Description for PV-TXSM11

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI DELETED

TSP2/[ ] The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.
[

CBI
DELETED

]

OR120018_BR_011870

AS1 Expression of this sequence alters the expression of marker genes.
[CBI DELETED]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

TSP2/[CBI DELETED] The TSP2 (Tissue-specific Promoter 2) plus intron is used to direct expression of foreign genes in plants.
[CBI DELETED]

TMG1 The expression of this gene is used as a marker for plant transformation.
[CBI DELETED]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CONSTRUCT DESCRIPTION FOR PV-TXCT23

PV-TXSM09 AND PV-TXSM12 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXSM09

See Description Above

OR120018_BR_011871

Construct Description for PV-TXSM12

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

TSP3/[ ] The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.
[CBI DELETED]

AS1 Expression of this sequence alters the expression of marker genes.
[CBI DELETED]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

TSP3/[ ] The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.
[CBI DELETED]

TMG1 The expression of this gene is used as a marker for plant transformation.
[CBI DELETED]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011872

CONSTRUCT DESCRIPTION FOR PV-TXCT28

PV-TXFR02 AND PV-TXSM09 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXFR02

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CMoVa/[CBI DELETED] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

[CBI DELETED]

Antifungal Protein Gene II Expression of AFP2 confers resistance to fungal diseases.

[CBI DELETED]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

Construct Description for PV-TXSM09

See Description Above

OR120018_BR_011873

FREE DELIVERY PARTICLE GUN (MONSANTO)

Introduction of DNA into plant tissue with the "biolistic" particle bombardment method has been described in detail by Klein et al. (1987, Nature 327: 70-73; 1988a, Bio/Technology 6: 559-563; and 1988b, Proc Natl Acad Sci USA 85: 4305-4309). The transgenic material in this application was produced using the commercially available particle delivery systems. Detailed instructions are available from the manufacturers. Briefly, DNA is precipitated onto microscopic (~1 μ diameter) tungsten or gold particles using calcium chloride and spermidine. A drop (2.5μl) of the coated particles is accelerated at a high velocity allowing the particles to penetrate the target plant cells, where the DNA is deposited and incorporated into the plant cell genome. The cells are incubated on a tissue culture medium which supports the growth of embryogenic callus. The introduced DNA contains a gene(s) encoding for resistance to either antibiotics (e.g., the NPTII gene for resistance to kanamycin and G418) or genes conferring herbicide resistance. The plant cells are grown in the presence of an appropriate antibiotic or herbicide, and only the transformed cells continue to grow. Plants are regenerated from the resistant embryogenic callus tissue, and are assayed for the presence of the introduced gene(s). The free delivery vectors are engineered to contain multiple chimeric plant expression genes in high copy E. coli plasmids.

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Kan

The free delivery vectors contain multiple chimeric plant expression genes engineered into pMON10081. The pMON10081 plasmid is a derivative of the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). It was constructed by fusing the 1.3 Kb FspI-DraI origin of replication fragment from pUC119, to the 1.3 Kb SmaI-HindIII (Klenow filled) fragment from pKC7 (Rao and Rogers 1979, Gene 7: 79). The pKC7 fragment contains the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance. The ß-lactamase gene conferring bacterial ampicillin resistance was completely deleted. Several chimeric plant expression genes can be introduced into pMON10081. These include the marker genes required for selection of the transformed plant tissue, and one or more chimeric genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

Item 13d. The plasmid vectors were constructed at the research laboratories of Monsanto Co. in St. Louis, Missouri. The initial wheat plants transformed with these vectors were also developed at the research laboratories of Monsanto Co. in St. Louis, Missouri, USA.

OR120018_BR_011874

Item 13e. A Detailed Description of the Purpose for the Regulated Article.

PROPOSED EXPERIMENTAL PROGRAM

Expt AGW96-1

Purpose of the test:

To evaluate the tolerance to Roundup herbicide of the transgenic lines under field conditions.

To evaluate agronomic performance, yield and yield components of the lines.

Investigators:

Principle Investigator:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Missouri (b) (6), (b) (7)(C), (b) (4)
Tel.: (b) (6), (b) (7)(C), (b) (4)
Fax.:

Site Investigators:

(b) (6), (b) (7)(C), (b) (4) North Dakota

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) ND (b) (6), (b) (7)(C), (b) (4)
Tel: (b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) Washington

Principle Researcher:

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) WA (b) (6), (b) (7)(C), (b) (4)
Tel/FAX: (b) (6), (b) (7)(C), (b) (4)

Location of Experiment

(b) (6), (b) (7)(C), (b) (4)

(b) (6), (b) (7)(C), (b) (4) WA (b) (6), (b) (7)(C), (b) (4)

OR120018_BR_011875

(b) (6), (b) (7)(C), (b) (4)

Site Description:

- (b) (6), (b) (7)(C), (b) (4) **Minnesota**

(b) (6), (b) (7)(C), (b) (4)

- (b) (6), (b) (7)(C), (b) (4) **Washington**

(b) (6), (b) (7)(C), (b) (4)

Field Test Design:

- Each plot will consist of one to four rows, 4-12 inches apart and up to 20 feet long.
- The trial will be established using a randomized complete block design.
- The number of replications will be determined by seed availability, however, it is anticipated that the experiment will have either 2 or 3 replications.

Genotypes:

- Up to 50 lines of homozygous and segregating progeny of lines transformed with plasmid vectors PV-TXSM09, PV-TXSM01 and PV-TXGT01.
- Non-transgenic Bobwhite and other control lines.

OR120018_BR_011876

Space requirements:

- The transgenic material will cover no more than 2.0 acres.
- The total area needed for the entire test will be no greater than 3.0 acres.

Isolation:

- The experiment will be surrounded by a 20 foot border of wheat to prevent outcrossing to wheat and other species not a part of this trial.

Tentative schedule:

- Planting: April 1 to May 31, 1996 depending on weather and seed availability.
- Harvest: The experiment will be harvested between August and October of 1996, depending on weather and date of planting.

Agronomic practices:

- Ground preparation and fertility: Ground preparation will follow normal practices for wheat. Fertilizer may be applied based on a soil test to bring the nutrient level up to that recommended for wheat. Additional fertilizer may be applied throughout the season as needed.
- Weed control: Weed control will follow acceptable practices for wheat by using labelled herbicides, experimental herbicides, and/or hand weeding.
- Disease control: Diseases may be controlled by the use of labelled fungicides for seed treatment and/or topical applications.
- Insect control: Insect pests will be monitored for their appearance in the field. Insecticides labelled to control insect pests that are present may be applied as needed, including seed treatments or topical applications.

Treatment

- The wheat will be treated with a 16 or 32 ounce per acre treatment of Roundup herbicide at either the 3rd or 6th leaf stage of growth.

Sampling:

- Leaf and other tissue samples may be taken from the plots and analyzed for disease infection and expression of the inserted trait. Such analyses will be conducted at Monsanto's research facility in Chesterfield, Missouri. A separate Limited Interstate movement permit will be applied for to cover these planned movements.

OR120018_BR_011877

Data Collection

- Roundup herbicide tolerance

  Evaluate the levels of chlorosis, necrosis and growth reduction 14 and 28 days after spraying.

  Evaluate the color and size of the anthers

  Measure the percent fertility of the treated plants.

- Agronomic traits

  The following will be recorded or evaluated; heading date, plant height, shattering and disease susceptibility

- Yield will be taken from all plots which produce grain.

Harvest procedures:

- The plots will either be harvested by hand or with a small plot combine. If the combine is used, it will be thoroughly cleaned following completion of the plot harvesting and before leaving the plot area.

Plant and seed disposal:

- After harvest, the test plot will be tilled to destroy the plant material. After tillage the plot area will be monitored for 1 year for surviving plants, which will be destroyed by hand, tillage or herbicide treatment. Wheat or another small grain will not be planted in this area for one year.

Item 13f. All research and procedures used in the production of the donor organism, recipient organism, vector or vector agent and the transgenic wheat were done utilizing level BL2 containment according to the NIH Guidelines for Recombinant DNA Research.

Item 13g. A Detailed Description of the Intended Destination

- (b) (6), (b) (7)(C), (b) (4) **Minnesota**

(b) (6), (b) (7)(C), (b) (4)

OR120018_BR_011878

- (b) (6), (b) (7)(C), (b) (4) Washington

(b) (6), (b) (7)(C), (b) (4)

Item 13h. Procedures, Processes and Safeguards that Will be Used to Prevent Escape and Dissemination of the Regulated Article.

The wheat seeds will be shipped to and from the field sites in compliance with 7 CFR 340.5 and 340.6 in containers fastened to preclude spillage. Movement will be by common carrier or air freight. The wheat seeds will be placed in secure storage with restricted access at the field sites prior to planting. None of the wheat seed or plant material produced in this experiment will enter commerce or will be consumed by domestic animals. Any plant tissue returned from the field site will be frozen and therefore not viable.

This trial will be clearly marked and separated from other wheat which may be growing in the vicinity. Such marking and isolation will prevent the accidental mixing of with conventional wheat varieties. The test will be terminated prior to harvest. After sampling, the test plot will be tilled or cut to destroy the plant material.

Item 13i. Proposed Method of Final Disposition of the Regulated Article

After harvest, the test plot will be tilled to destroy the plant material. The plot area will be monitored for one year following harvest, and any surviving plants will be destroyed by hand, tillage or herbicide treatment.

OR120018_BR_011879

FILE

31 JAN 1996

Dr. Cheryl Fox, Supervisor
Minnesota Department of Agriculture
90 West Plato Boulevard
St. Paul, MN 55107

Re: APHIS Review of the Monsanto Company Application to Field Test Genetically Engineered Wheat Plants; Accession Number 96-019-03r

Dear Dr. Fox:

This letter contains our review of an application submitted by Monsanto Company for a permit that would allow the field testing of genetically engineered wheat plants. The wheat plants were genetically engineered to express resistance fungal infections and to the herbicide glyphosate. The field tests are scheduled to start March 31 1996 in two states, Washington (Walla Walla) and Minnesota (Clay County).

This application was submitted pursuant to regulations found in 7 CFR Part 340 which regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products which are regulated articles. The regulations, which were promulgated pursuant to authority granted by the Federal Plant Pest Act and Plant Quarantine Act, require that a person obtain a permit from the Animal and Plant Health Inspection Service (APHIS) prior to introducing a regulated article.

For purposes of this submission, these genetically engineered wheat plants are deemed "regulated articles" (as defined in §340.1 of the regulations) because they contain DNA sequences that were derived from plant pests. Under the regulations, one basis for designating an organism as a regulated article is that it is genetically engineered (as defined in §340.1) from a donor organism, recipient organism, or vector or vector agent, which is listed in §340.2 of the regulations, and the listed organism is a plant pest (as defined in §340.1).

These plants are deemed regulated articles because certain nucleic acids sequences derived from known plant pests (*Agrobacterium tumefaciens*, and cauliflower mosaic virus) have been inserted into the plant's genome.

Pursuant to the procedures set forth in §340.3 of the regulations, we have prepared our assessment in this letter for your notification and review. This serves to give notice to the state and to provide the

OR120018_BR_011880

opportunity for the State to expressly indicate concurrence or nonconcurrence with our review. Please review the enclosed application documents and return acknowledgement, associated comments, and concurrence or reasons for nonconcurrence (if applicable) to APHIS within 30 days from the date of this letter.

Please use the enclosed form, and use additional sheets if needed for your response. It is very important that our office receive comments and opinions from State regulatory officials regarding the issuance of permits for the release of genetically engineered organisms into the environment.

On the basis of our review of this application, we have concluded that the controlled field testing of these genetically engineered wheat plants will not present any risk of plant pest introduction or dissemination for the reasons cited below.

1. Environmental Impacts Related to the Recipient. There appears to be little risk of the transgenic plant material or the introduced genes escaping the test site or surviving independently after termination of the experiment. Standard breeding practices, including the use of border rows and appropriate isolation distances, will be used to prevent mechanical mixing and unwanted introduction of transgenic material into neighboring wheat plants via pollen. Wheat is normally self-pollinated. The trial will be isolated from other wheat according to the standards set forth by the Association of Official Seed Certifying Agencies, i.e., by a 20 ft. strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat. Harvesting equipment, if used, will be thoroughly cleaned prior to leaving the area.

2. Environmental Impacts Related to the Donor. The transgenic wheat lines have been engineered with various combinations of genes for resistance to herbicide glyphosate and fungal infection and selectable marker genes. The *nptII* gene conferring resistance to the antibiotic kanamycin that encodes the enzyme neomycin phosphotransferase was used as a selectable marker. The marker genes are used to facilitate the selection of transformed plant tissue either in the laboratory or in the field. Although some DNA sequences were derived from plant pathogens, none of the introduced genes nor the regulatory sequences used to express these genes have any inherent pest characteristics or pose a risk to plant health.

3. Environmental Impacts Related to the Vector and Vector Agent. The genes were transferred to wheat via the "biolistic" particle bombardment method. This is a well characterized transformation system which integrates the donor genes into the chromosome of the recipient plant cell. These donor sequences then are maintained and inherited as any other genes of the plant cell.

OR120018_BR_011881

4. Quarantine of Organism and Final Disposition. The test site is expected to provide adequate physical security. Site monitoring and management practices that create a nonpropagative environment should provide the necessary degree of both biological and physical containment. The field plots will be disked to destroy plants and incorporate stubble and seeds. The plots will be monitored for volunteer plants for one year. Volunteer plants will be destroyed by disking and/or herbicide treatment. The containment measures described in the application should be sufficient to prevent any unplanned releases of the transgenic plant material.

Staff Contact

If you have any questions about this application or our review, please contact Dr. Ved Malik, Biotechnologist, at Area Code (301) 734-6774 or facsimile number (301) 734-8669. Please refer to permit application number 96-019-03r in your correspondence regarding this application. APHIS hopes to maintain its excellent working relationship with your State and encourages your participation and comments prior to our final decision.

Sincerely,

Ved Malik, Ph.D.
Biotechnologist
Biotechnology Permits

2 Enclosures
Permit Application 96-019-03r
State Response Form

cc:
J. Burch, PPQ, Moorestown, NJ
File 96-019-03r

APHIS:BBEP:BP:VMALIK:RAS:734-7612:1/25/96:9601903.STA

OR120018_BR_011882

FILE

31 JAN 1996

Dr. Daniel Williams
Plant Services
Washington Department of Agriculture
1111 Washington Street
Olympia, WA 98504

Re: APHIS Review of the Monsanto Company Application to Field Test Genetically Engineered Wheat Plants; Accession Number 96-019-03r

Dear Dr. Williams:

This letter contains our review of an application submitted by Monsanto Company for a permit that would allow the field testing of genetically engineered wheat plants. The wheat plants were genetically engineered to express resistance fungal infections and to the herbicide glyphosate. The field tests are scheduled to start March 31 1996 in two states, Washington (Walla Walla) and Minnesota (Clay County).

This application was submitted pursuant to regulations found in 7 CFR Part 340 which regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products which are regulated articles. The regulations, which were promulgated pursuant to authority granted by the Federal Plant Pest Act and Plant Quarantine Act, require that a person obtain a permit from the Animal and Plant Health Inspection Service (APHIS) prior to introducing a regulated article.

For purposes of this submission, these genetically engineered wheat plants are deemed "regulated articles" (as defined in §340.1 of the regulations) because they contain DNA sequences that were derived from plant pests. Under the regulations, one basis for designating an organism as a regulated article is that it is genetically engineered (as defined in §340.1) from a donor organism, recipient organism, or vector or vector agent, which is listed in §340.2 of the regulations, and the listed organism is a plant pest (as defined in §340.1).

These plants are deemed regulated articles because certain nucleic acids sequences derived from known plant pests (*Agrobacterium tumefaciens*, and cauliflower mosaic virus) have been inserted into the plant's genome.

Pursuant to the procedures set forth in §340.3 of the regulations, we have prepared our assessment in this letter for your notification and review. This serves to give notice to the state and to provide the

OR120018_BR_011883

opportunity for the State to expressly indicate concurrence or nonconcurrence with our review. Please review the enclosed application documents and return acknowledgement, associated comments, and concurrence or reasons for nonconcurrence (if applicable) to APHIS within 30 days from the date of this letter.

Please use the enclosed form, and use additional sheets if needed for your response. It is very important that our office receive comments and opinions from State regulatory officials regarding the issuance of permits for the release of genetically engineered organisms into the environment.

On the basis of our review of this application, we have concluded that the controlled field testing of these genetically engineered wheat plants will not present any risk of plant pest introduction or dissemination for the reasons cited below.

1. Environmental Impacts Related to the Recipient. There appears to be little risk of the transgenic plant material or the introduced genes escaping the test site or surviving independently after termination of the experiment. Standard breeding practices, including the use of border rows and appropriate isolation distances, will be used to prevent mechanical mixing and unwanted introduction of transgenic material into neighboring wheat plants via pollen. Wheat is normally self-pollinated. The trial will be isolated from other wheat according to the standards set forth by the Association of Official Seed Certifying Agencies, i.e., by a 20 ft. strip of ground adequate to prevent mechanical mixtures. The strip may be either mowed, uncropped, or planted to a crop other than wheat. Harvesting equipment, if used, will be thoroughly cleaned prior to leaving the area.

2. Environmental Impacts Related to the Donor. The transgenic wheat lines have been engineered with various combinations of genes for resistance to herbicide glyphosate and fungal infection and selectable marker genes. The *nptII* gene conferring resistance to the antibiotic kanamycin that encodes the enzyme neomycin phosphotransferase was used as a selectable marker. The marker genes are used to facilitate the selection of transformed plant tissue either in the laboratory or in the field. Although some DNA sequences were derived from plant pathogens, none of the introduced genes nor the regulatory sequences used to express these genes have any inherent pest characteristics or pose a risk to plant health.

3. Environmental Impacts Related to the Vector and Vector Agent. The genes were transferred to wheat via the "biolistic" particle bombardment method. This is a well characterized transformation system which integrates the donor genes into the chromosome of the recipient plant cell. These donor sequences then are maintained and inherited as any other genes of the plant cell.

OR120018_BR_011884

4. Quarantine of Organism and Final Disposition. The test site is expected to provide adequate physical security. Site monitoring and management practices that create a nonpropagative environment should provide the necessary degree of both biological and physical containment. The field plots will be disked to destroy plants and incorporate stubble and seeds. The plots will be monitored for volunteer plants for one year. Volunteer plants will be destroyed by disking and/or herbicide treatment. The containment measures described in the application should be sufficient to prevent any unplanned releases of the transgenic plant material.

Staff Contact

If you have any questions about this application or our review, please contact Dr. Ved Malik, Biotechnologist, at Area Code (301) 734-6774 or facsimile number (301) 734-8669. Please refer to permit application number 96-019-03r in your correspondence regarding this application. APHIS hopes to maintain its excellent working relationship with your State and encourages your participation and comments prior to our final decision.

Sincerely,

Ved Malik, Ph.D.
Biotechnologist
Biotechnology Permits

2 Enclosures
Permit Application 96-019-03r
State Response Form

cc:
R. Stoaks, PPQ, Sacramento, CA
File 96-019-03r

APHIS:BBEP:BP:VMALIK:RAS:734-7612:1/25/96:9601903.STA

OR120018_BR_011885

FILE COPY

APHIS APPLICATION NO. 96-019-03r
DATE: 1/31/96

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

_____ State concurs with APHIS' initial review.

__X__ State concurs with APHIS' initial review and offers the following comments (use additional sheets if necessary):

Minnesota requires a separate permit. The application is currently being prepared. Planting may not occur prior to issuance of a MDA permit

_____ State does not concur with APHIS' initial review and offers the following reasons for nonconcurrence (use additional sheets if necessary):

Name of State Official: Cheryl C. Fox

Title: Biotechnologist

Agency or Department: MN Dept. of Ag

Address: 90 W. Plato Blvd.

City, State, Zip Code: St. Paul, MN 55107

Signature: Cheryl C. Fox

Date: 2/8/96

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

DR. VED MALIK
USDA, APHIS, BBEP
Biotechnology Permits
4700 River Road, Unit 147
Riverdale, MD 20737

RECEIVED 4/17/96

OR120018_BR_011886

FILE COPY

APHIS APPLICATION NO. 96-019-03r
DATE: 1/31/96

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

___√___ State concurs with APHIS' initial review.

_____ State concurs with APHIS' initial review and offers the following comments (use additional sheets if necessary):

_____ State does not concur with APHIS' initial review and offers the following reasons for nonconcurrence (use additional sheets if necessary):

Name of State Official: Daniel Williams

Title: State Plant Pathologist

Agency or Department:

Address:

City, State, Zip Code:

Signature: (b) (6), (b) (7)(C)

Date: 2/14/96

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

DR. VED MALIK
USDA, APHIS, BBEP
Biotechnology Permits
4700 River Road, Unit 147
Riverdale, MD 20737

RECEIVED 2/16/96

Supplemental Permit Conditions

Permit Number 96-019-03r

1. Biotechnology, Biologics, and Environmental Protection (BBEP) or a Regional Biotechnologist will conduct an inspection of the test site at the beginning of the test. The permittee is required to notify the State regulatory official, and the appropriate Regional Biotechnologist (see attached map) at least 1-week before the test begins.

2. Additional inspections may be conducted by the Regional Biotechnologist. The permittee is required to notify the Regional Biotechnologist and the State Official at least 1-week before termination of the experiment.

3. **A field test data report must be submitted within 12 months after the permit issuance date. If a field test is still in progress at 12 months or any multiple of 12 months after the permit issuance date, additional field test data reports must be submitted to APHIS and State Official within subsequent 12 month periods. Final reports for those field tests lasting more than 12 months must be submitted to APHIS and State Official 6 months after the termination of the field test.** Field test reports shall include: methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment. We encourage the inclusion of other types of data if the applicant anticipates submission of a petition for determination of non-regulated status for their regulated article. APHIS views these data reports as critical to our assessment of plant pest risk and development of regulatory policies based on the best scientific evidence. Failure by an applicant to provide data reports in a timely manner for a field trial may result in the withholding of permission by APHIS for future field trials.

Confidential Business Information (CBI) will be handled according to the APHIS policy statement at 50 FR 38561-63.

4. The test site shall be monitored for any volunteer plants after the completion of the test until the end of the following growing season for that crop in the area.

5. BBEP should be notified of any proposed changes to the protocol referenced in the permit application.

6. This approved Biotechnology Permit (APHIS form #2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (1) for the use of any non-genetically engineered plant pest or pathogens as challenge inoculum; (2) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (3) experimental use of unregistered chemical; and (4) food or feed use of genetically engineered crops harvested from the field experiment.

OR120018_BR_011888

96-019-03

Assessment Worksheet (AW) for Release Permits - Biotechnology Permits
Version 1.0 - March 3, 1995

BP's Permitting activities are categorically exempt from the NEPA requirements if the field test permit is for a plant species that meets the following criteria:

(1) The plant species has previously been the subject of an EA prior to release under APHIS permit, and
(2) The "trait" engineered into the plant is not new and its introduction in the plant does not "raise any new issues" with respect to environmental impacts

If the reviewer can answer "yes" to point #1, then the rest of the AW should be completed in order to be able to answer point #2. If, after completing the AW, the reviewer can answer "yes" to point #2, there is no need for an EA before the permit is issued. The reviewer should place the AW in the file for the permit.

If, after completing the AW, the reviewer can not answer "yes" to both points #1 and #2 above, then it will be necessary to prepare an EA before a permit is issued.

Complete the required for database information, including

1. Indicate all gene(s) and source organisms: [GENE LIST] FR HR(YES) YES

2. Indicate recipient species: wheat

THEN,

3. For insect resistant (IR) phenotype, check site(s) of tests for there threatened and endangered species:

_____ NO, threatened and endangered species are not likely to be affected
_____ YES, threatened and endangered species likely to be affected

4. Containment protocol:

_____ proposed protocol is adequate (at least as good as that used for APHIS Permit_____)
_____ proposed protocol is inadequate and modified in consultation with applicant in the following way(s):

OR120018_BR_011889

5. Devitalization and monitoring for volunteers:
✓ proposed protocol is adequate (at least as good as that used for APHIS Permit_____)
_____ proposed protocol is inadequate and modified in consultation with applicant in the following way(s):

6. Physical (separated from surrounding plants to prevent mixing):

_____ proposed protocol is adequate (at least as good as that used for APHIS Permit_____)

_____ proposed protocol is inadequate and modified in consultation with applicant in the following way(s):

NOTE: ITEMS 7 & 8 ARE ALSO INTENDED TO HELP THE BIOTECHNOLOGIST FACILITATE ANY OTHER REGULATORY REQUIREMENTS THAT THE APPLICANT MAY FACE (FOR EXAMPLE, REQUIREMENTS OF APHIS-PPQ, EPA, OR THE STATES)

7. Will there be challenge inoculations as part of the test?
✓ NO
_____ YES (Challenge viral inocula may "raise new issues", such as potential for recombination, and thereby trigger the need for a full EA.)

8. Will the applicant need other permits (such as interstate movement of plant pathogens)
✓ NO
_____ YES

9. Conclusion regarding impact on the environment (equivalent to FONSI).

OR120018_BR_011890

For example: If any of the following criteria are true for a release permit application, we will prepare an EA:

1. *New crop species (never field tested before under APHIS Permit)*
2. *Regulated article is a microorganism*
3. *The trait(s) introduced would not qualify under the NOTIFICATION eligibility criteria*

    * *an exception would be virus genes (such as replicase, movement proteins, etc.) that would not qualify under notification, but we have previously considered these genes in the <u>same</u> crop (in consideration of potential recombination among viruses that can infect the same host species). This would be an example where the trait and plant have been evaluated before, but the consideration of new recombination opportunities would "raise new issues" (see the first two criteria on page one).*

OR120018_BR_011891

FILE COPY

APHIS APPLICATION NO. 96-019-03r
DATE: 1/31/96

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

_____ State concurs with APHIS' initial review.

_X_ State concurs with APHIS' initial review and offers the following comments (use additional sheets if necessary):

Minnesota requires a separate permit. The application is currently being prepared. Planting may not occur prior to issuance of a MDA permit

_____ State does not concur with APHIS' initial review and offers the following reasons for nonconcurrence (use additional sheets if necessary):

Name of State Official: Cheryl C. Fox

Title: Biotechnologist

Agency or Department: MN Dept. of Ag

Address: 90 W. Plato Blvd.

City, State, Zip Code: St. Paul, MN 55107

Signature: (b) (6), (b) (7)(C)

Date: 2/8/96

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

DR. VED MALIK
USDA, APHIS, BBEP
Biotechnology Permits
4700 River Road, Unit 147
Riverdale, MD 20737

RECEIVED 4/17

FILE COPY

APHIS APPLICATION NO. 96-019-03r
DATE: 1/31/96

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

√ State concurs with APHIS' initial review.

_____ State concurs with APHIS' initial review and offers the following comments (use additional sheets if necessary):

_____ State does not concur with APHIS' initial review and offers the following reasons for nonconcurrence (use additional sheets if necessary):

Name of State Official: Daniel Williams

Title: State Plant Pathologist

Agency or Department:

Address:

City, State, Zip Code:

Signature: (b) (6), (b) (7)(C) WA

Date: 2/14/96

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

DR. VED MALIK
USDA, APHIS, BBEP
Biotechnology Permits
4700 River Road, Unit 147
Riverdale, MD 20737

RECEIVED 2/16/96

FILE

APR 23 1996

Mr. Terry Stone
Regulatory Affairs Manager
Monsanto Agricultural Group
700 Chesterfield Parkway North, BB3A
Chesterfield, MO 63198

Subject: Biotechnology Permit Number 96-019-03r to Conduct a Planned Release of Genetically Engineered *Wheat* Plants

Dear Mr. Stone:

The above permit has been approved after a Finding of No Significant Impact (FONSI) and a finding that the genetically engineered organisms do not present a risk of plant pest introduction or dissemination. You must adhere to the standard and supplemental conditions enclosed.

This permit should not be taken as any type of efficacy determination of the genetically engineered organisms.

Sincerely,

A. Foudin

Arnold S. Foudin, Ph.D.
Deputy Director
Biotechnology Permits

Enclosure:
Permit 96-019-03r
Supplemental Permit Conditions
Standard Permit Conditions
Map - Regional Biotechnologists

cc:
C. Fox, MN Dept. Agriculture, St. Paul, MN 55107
D. Williams, WA Dept. of Agriculture, Olympia, WA 98504
J. Burch, NER-PPQ, Moorestown, NJ 08057
R. Stoaks, PPQ, Sacramento, CA 95827
File 96-019-03r

BP:BBEP:APHIS:VMALIK:RAS:734-7612:4/19/96:I:\9601903.IS2

OR120018_BR_011894

6/14/96 12:05 pm Release Tracking Sheet

DRAFT

Bp number: 96-166-01r

Intro type: Release Renewal Permit:
Received: 6/14/96 Clock stop: Clock start: Due: 10/12/96
Institution: Monsanto
Resp person: (b) (6), (b) (7)(C)
Recipient: Wheat
Status: Pending Sites: 1 Acre:
Reviewer: JW
CBI status: CBI
Phenotype: HT - Glyphosate tolerant
Comments:
Parsed name: (b) (6), (b) (7)(C)
Address1: Monsanto Company
Address2: 700 Chesterfield Parkway North
Address3:
Address4:
City/State: St. Louis, MO 63198
Telephone: (b) (6), (b) (7)(C) Fax: 314-537-7085

		Initial	Date
1.	[V] Assign Bp number and initial data entry	[ ]	[6/14/96]
2.	[ ] Letter of notification to Applicant	[ ]	[ ]
3.	[V] File and this tracking sheet to reviewer	[ ]	[6/14/96]
4.	[V] Letter of preliminary assessment to State	[ ]	[7/29/96]
5.	[ ] Reviewer checks data entries and returns this sheet to permit unit	[ ]	[ ]
6.	[ ] State response listed by State/Region/Sites		
	AZ WR 1 State Response	[ ]	[8/13/96]
7.	[ ] Permit issued or denied	[ ]	[8/29/96]
8.	[ ] Enter final data into database	[ ]	[8/29/96]

OR120018_BR_011895

Notice

Confidential Business Information

Some information in the attached material may be entitled to treatment as trade se
proprietary data under Section(b)(4) of the Freedom of Information Act (FOIA) [5 U
552(b)(4)].

Any person handling or using the attached data in any way is responsible for preve
unauthorized disclosure during possession.

Maintain this document under secure conditions.

Return to the Document Control Officer after use.

This application deals with:

MONSANTO- wheat - HT - State = AZ

Identification Number:

96-166-01R

The attached information is not to be published, reproduced, publicly discussed, inclu
response to a FOIA request, or otherwise released without the explicit written authori
of the appropriate division director or designee.

Please disqualify yourself if there is any potential Conflict of Interest

OR120018_BR_011896

This application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq. and the Plant Quarantine Act (7 U.S.C. 151 et seq.)). The information will be used to determine eligibility to receive all types of permits. No permit shall be issued until this application has been approved.

CONTAINS CBI

See reverse side for additional information

FORM APPROVED
OMB NO. 0579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

(Genetically Engineered Organisms or Products)

96-113PR

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

1. NAME AND ADDRESS OF APPLICANT

(b) (6), (b) (7)(C)

Monsanto Company/BB3A
700 Chesterfield Parkway North
St. Louis, MO 63198

96-166-01R

2. PERMIT REQUESTED ("X" one)

- ☐ Limited - Interstate Movement
- ☐ Limited - Importation
- ☒ Release into the Environment
- ☐ Courtesy Permit

3. THIS REQUEST IS *("X" one)*

- ☒ New
- ☐ Renewal
- ☐ Supplemental

4. TELEPHONE NUMBER

(b) (6), (b) (7)(C)

5. MEANS OF MOVEMENT

- ☐ Mail
- ☐ Baggage or Handcarried
- ☐ Common Carrier
- By whom _____

6. GIVE THE FOLLOWING *(if applicable) (if more space is needed, attach additional sheet)*

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism:	See Attached			
b. Recipient Organism:				
c. Vector or Vector Agent:				
d. Regulated Organism or Product:				
e. If product, list names of constituents:				

7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS

NA

8. DATE *(or inclusive dates of period)* **OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE**

October 1, 1996 - September 30, 1997

9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

See Attached

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

See Attached

11. ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* **ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT**

None

12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

Not Applicable

13. SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON	15. PRINTED NAME AND TITLE	16. DATE
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	June 11, 1996

FOR APHIS USE ONLY

State Notification Sent	State Review Received	Permit Issued ☐ Yes ☐ No
Date of Determination	Permit No.	No. of Permit Labels Issued
Supplemental Conditions Enclosed ☐ Yes ☐ No		
Signature of BBEP Official	Date	Expiration Date

OR120018_BR_011897

APHIS FORM 2000 (JUL 89)

Replaces PPQ Form 1001 which may be used.

(continued on reverse)

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Kan

The free delivery vectors contain multiple chimeric plant expression genes engineered into pMON10081. The pMON10081 plasmid is a derivative of the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). It was constructed by fusing the 1.3 Kb FspI-DraI origin of replication fragment from pUC119, to the 1.3 Kb SmaI-HindIII (Klenow filled) fragment from pKC7 (Rao and Rogers 1979, Gene 7: 79). The pKC7 fragment contains the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance. The ß-lactamase gene conferring bacterial ampicillin resistance was completely deleted. Several chimeric plant expression genes can be introduced into pMON10081. These include the marker genes required for selection of the transformed plant tissue, and one or more chimeric genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

OR120018_BR_011898

Item 13d. The plasmid vectors were constructed at the research laboratories of Monsanto Co. in St. Louis, Missouri. The initial wheat plants transformed with these vectors were also developed at the research laboratories of Monsanto Co. in St. Louis, Missouri, USA.

Item 13e. The information regarding the description of the proposed experiment for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design is found in the following protocol:

Purpose of the test:

The purpose is to evaluate the tolerance to Roundup® herbicide of the transgenic lines under field conditions, and to evaluate agronomic performance, yield and yield components of the lines.

Investigators:

Principle Investigator

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) MO (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C) (fax)

Site Investigator

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) AZ (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

Site Security:

This trials will be located on a privately owned farm. The owner has been instructed as to the nature of the experiment and the need to maintain these plants and seed separate from any other wheat not a part of this trial. Generally, the public is not allowed free access to public land, and the cooperator and owner will be instructed as to the need to frequently observe the plots for any signs of crop damage or vandalism.

OR120018_BR_011899

Agronomic Practices:

Ground preparation and fertility: ground preparation will follow normal practices for wheat. Fertilizer may be applied based on a soil test to bring the nutrient level up to that recommended for wheat. Additional fertilizer may be applied throughout the season as needed.

Weed control: Weed control will follow acceptable practices for wheat by using labelled herbicides, experimental herbicides, and/or hand weeding.

Disease control: Diseases may be controlled by the use of labelled fungicides for seed treatment and/or topical applications.

Insect control: Insect pests will be monitored for their appearance in the field. Insecticides labelled to control insect pests that are present may be applied as needed, including seed treatments or topical applications.

Isolation:

The experiment will be surrounded by a 20-foot border of wheat to prevent outcrossing to wheat or other species not a part of this trial.

Monitoring protocols of adequate duration are required to ensure that all volunteers resulting from the field testing of a genetically engineered crop are iddentified and eliminated.

Plot Design:

The experiment will be a randomized complete block with up to three replicates per treatment. The plots will be sprayed with 16 and 32 oz./A Roundup® at 2-4 and >5 leaf stages. The total area to be planted to the transgenic plants will be up to one acre.

Tentative Schedule:

Planting will be between October 15 1996 - December 15, 1996 depending on the weather and seed availability. Harvesting will be between April 1, 1997 - May 30, 1997 depending on weather and date of planting.

Harvest Procedures:

The plots will either be harvested by hand or with a small plot combine. If the combine is used, it will be thoroughly cleaned following completion of the plot harvesting and before leaving the plot area.

After harvesting, the test plots will be tilled to destroy the plant material. The plot area will be monitored for one year for surviving plants, which will be destroyed by hand, tillage or herbicide. Wheat or another small grain crop will not be planted in this area for one year.

OR120018_BR_011900

Item 13f. To avoid accidental mixing and loss, the shipping and maintenance of genetic engineered seeds and plants will include double containment, and devitalization of seeds and other material capable of propagation prior to disposal.

Item 13g. The wheat seed will be shipped to the location specified in item 10. Once received, the seed will be stored in a contained storage facility and used for field release. Any unused seed will be retained for later use or returned to Monsanto, St. Louis.

Item 13h. Once received, the seed will be stored in a locked storage facility and used for field release.

Item 13i. Any unused seed will be retained for later use or returned to Monsanto, St. Louis. For future use, the field will be planted to a crop other than wheat. Any wheat volunteer plants will be removed during the following season.

OR120018_BR_011901

APHIS FORM 2000 ATTACHMENTS

This request for a Release into the Environment Permit is to allow the field testing of transgenic wheat which has been modified to be herbicide tolerant. All of the information required to support this permit is found in this application.

The plasmid vector constructs that will be a part of these field experiments are: PV-TXCT01, PV-TXCT15, PV-TXCT23 and PV-TXGT02.

Item 6. The following is the information required to identify the donor, recipient and regulated organisms and vector agent:

For the plasmid vector PV-TXCT01 (PV-TXGT01 + PV-TXSM01):

Plasmid Vector PV-TXGT01:

Name	Scientific Name	Common Name
a. Donor Organism	(b) (4) *Arabidopsis thaliana* *Agrobacterium sp.* *Achromobacter* sp.	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector or Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid Vector PV-TXSM01:

Name	Scientific Name	Common Name
a. Donor Organism	(b) (4) *Escherichia coli*	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

OR120018_BR_011902

b. For the plasmid vector PV-TXCT15 (PV-TXFR05 + PV-TXSM09)

Plasmid Vector PV-TXFR05:

Name	Scientific Name	Common Name
a. Donor Organism	(b) (4)	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid Vector PV-TXSM09:

Name	Scientific Name	Common Name
a. Donor Organism	(b) (4) *Agrobacterium sp.*	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

OR120018_BR_011903

CONTAINS CBI

c. For Construct PV-TXCT23 - (PV-TXSM09 + PV-TXSM12)

Plasmid Vector PV-TXSM09:

Name	Scientific Name	Common Name
a. Donor Organism	(b) (4) *Agrobacterium sp.*	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid Vector PV-TXSM12:

Name	Scientific Name	Common Name
a. Donor Organism	*Agrobacterium sp.* (b) (4)	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

d. For Plasmid Vector PV-TXGT02

Name	Scientific Name	Common Name
a. Donor Organism	(b) (4) *Arabidopsis thaliana* *Agrobacterium sp.*	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

OR120018_BR_011904

Item 9. The donor, recipient and vector organisms were collected in the United States. The vector construct and transgenic wheat were developed by Monsanto at the Chesterfield Village Laboratories. The seed was generated from laboratory trials conducted at Monsanto Company.

Item 10. The location of the field experiment:

Yuma County, Arizona

[redacted]

Item 13a. The transgenic wheat that is the subject of this permit request was developed by scientists at Monsanto.

Item 13b. All of the testing, to date, suggests that the modified plants are identical morphologically, structurally, physiologically, etc., to the non-modified parental variety.

Item 13c. The following is a detailed description of the molecular biology of the system used to produce the regulated article.

OR120018_BR_011905

CONTAINS CBI

Construct Descriptions for PV-TXCT01

PV-TXGT01 AND TXSM01 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXGT01

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CMoVa/(b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI (b) (4)

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants. CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature CP4 protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CMoVa/(b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI (b) (4)

OR120018_BR_011906

CONTAINS CBI

Constructs PV-TXCT01 (Cont'd)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.
CTP1-GMEsyn is a gene fusion composed of the N-terminal 0.26 Kb chloroplast transit peptide sequence derived from the *Arabidopsis thaliana* SSU 1a gene (CTP1) (Timko et al. 1988, The Impact of Chemistry on Biotechnology, ACS Books, 279-295), and the C-terminal 1.3 Kb synthetic gene sequence (GMEsyn). GMEsyn gene encodes the enzyme glyphosate oxidoreductase from an *Achromobacter* sp. strain LBAA which catalyzes the conversion of glyphosate to herbicidally inactive products, aminomethylphosphonate and glyoxylate. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature GMEsyn protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

Construct Description for PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**(b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al. 1987, Science 236:1299-1302)

CBI [redacted]

GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011907

CONSTRUCT DESCRIPTION FOR PV-TXCT15

PV-TXFR05 AND PV-TXSM09 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXFR05

This construct is a free delivery: pUC-Kan vector containing one gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CBI **CMP1/**(b) (4) The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI (b) (4)

Antifungal Protein Gene II Expression of AFP2 confers resistance to fungal diseases.

CBI (b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

Construct Description for PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**(b) (4) A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al. 1987, Science 236:1299-1302).

CBI (b) (4)

OR120018_BR_011908

Construct Description for PV-TXCT15 (Cont'd)

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants. CTP4-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Petunia hybrida* EPSPS gene (CTP4) (Shah et al. 1986, Science 233: 478-481), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature CP4 protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011909

CONTAINS CBI

CONSTRUCT DESCRIPTION FOR PV-TXCT23

PV-TXSM09 AND PV-TXSM12 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/**[redacted] A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [redacted]

CTP4-CP4 Expression of CTP4-CP4 confers glyphosate tolerance in plants. CTP4-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Petunia hybrida* EPSPS gene (CTP4) (Shah et al. 1986, Science 233: 478-481), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature CP4 protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011910

Construct Description for PV-TXCT23 (Cont'd)

Construct Description for PV-TXSM12

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **TSP3/**(b) (4) The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

CBI (b) (4)

AS1 Expression of this sequence alters the expression of marker genes.

CBI (b) (4)

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI **TSP3/**(b) (4) The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

CBI (b) (4)

CBI **TMG1** The expression of this gene is used as a marker for plant transformation. [TMG1 is a 1.8 Kb coding region of the ß-glucuronidase gene (GUS) from *Escherichia coli*. (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011911

CONSTRUCT DESCRIPTION FOR PV-TXGT02

This construct is a free delivery: pUC-Kan vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMP1/**[(b) (4)] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [(b) (4)]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants. CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature CP4 protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI **CMP1/**[(b) (4)] The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [(b) (4)]

OR120018_BR_011912

Construct Description for PV-TXGT02 (Cont'd)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.
CTP1-GMEsyn is a gene fusion composed of the N-terminal 0.26 Kb chloroplast transit peptide sequence derived from the *Arabidopsis thaliana* SSU 1a gene (CTP1) (Timko et al. 1988, The Impact of Chemistry on Biotechnology, ACS Books, 279-295), and the C-terminal 1.3 Kb synthetic gene sequence (GMEsyn). GMEsyn gene encodes the enzyme glyphosate oxidoreductase which catalyzes the conversion of glyphosate to herbicidally inactive products, aminomethylphosphonate and glyoxylate. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature GMEsyn protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011913

FREE DELIVERY PARTICLE GUN (MONSANTO)

Introduction of DNA into plant tissue with the "biolistic" particle bombardment method has been described in detail by Klein et al. (1987, Nature 327: 70-73; 1988a, Bio/Technology 6: 559-563; and 1988b, Proc Natl Acad Sci USA 85: 4305-4309). The transgenic material in this application was produced using the commercially available particle delivery systems. Detailed instructions are available from the manufacturers. Briefly, DNA is precipitated onto microscopic (~1 μ diameter) tungsten or gold particles using calcium chloride and spermidine. A drop (2.5μl) of the coated particles is accelerated at a high velocity allowing the particles to penetrate the target plant cells, where the DNA is deposited and incorporated into the plant cell genome. The cells are incubated on a tissue culture medium which supports the growth of embryogenic callus. The introduced DNA contains a gene(s) encoding for resistance to either antibiotics (e.g., the NPTII gene for resistance to kanamycin and G418) or genes conferring herbicide resistance. The plant cells are grown in the presence of an appropriate antibiotic or herbicide, and only the transformed cells continue to grow. Plants are regenerated from the resistant embryogenic callus tissue, and are assayed for the presence of the introduced gene(s). The free delivery vectors are engineered to contain multiple chimeric plant expression genes in high copy E. coli plasmids.

OR120018_BR_011914

CONFIDENTIAL BUSINESS INFORMATION JUSTIFICATION

The information claimed as confidential within this application consists of donor organisms and gene descriptions. The gene description category includes names and information about genes, promoters and expressed traits.

LEGAL BACKGROUND

The Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, specifically exempts from release "trade secrets and commercial or financial information obtained from a person and privileged or confidential" ("Exemption 4"). 5 U.S.C. § 552(b)(4). Exemption 4 applies where the disclosure of information would be likely to cause substantial harm to the competitive position of the owner, or where, in the case of voluntarily submitted information, the submitter would be less likely in the future to share data with the agency voluntarily. National Parks & Conservation Association v. Morton, 498 F.2d 765, 770 (D.C.Cir. 1974); Gulf & Western Industries, Inc. v. U.S., 615 F.2d 527, 530 (D.C.Cir. 1979).

A party seeking to demonstrate "substantial competitive harm" need not show actual competitive harm, but must only demonstrate the presence of competition and the likelihood of substantial competitive injury. Id. at 530; National Parks & Conservation Association v. Kleppe, 547 F.2d 673, 679 (D.C.Cir. 1976); Miami Herald Pub. Co. v. U.S. Small Business Administration, 670 F.2d 610, 614 (5th Cir. Unit B 1982).

For the purposes of FOIA, courts have defined the term "trade secret" to mean a "secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C.Cir. 1983); Anderson v. Dept. of Health & Human Services, 907 F.2d 936, 943-44 (lOth Cir. 1990).

Information on gene description and commercial development falls squarely within this definition, and is the type of information accorded trade secret protection by the courts under Exemption 4 of the Freedom of Information Act. It is well established that information on the formulation and chemistry of a product should be treated as confidential for FOIA purposes. See, e.g., Anderson v. Dept. of Health & Human Services, 907 F.2d 936 (lOth Cir. 1990). This is exactly the type of information provided by each and every subcategory listed above in the gene description category. Where, as in the case of the Monsanto products subject to this FOIA request, the development time and costs of the product have been substantial and the information can only be obtained by competitors at considerable cost, disclosure is prohibited. Greenberg v. Food and Drug Administration, 803 F.2d at [213, 1216-1218 (D.C. Cir. 1986); Worthington Compressors, Inc. v. Costie, 622 F.2d 45, 51-52 (D.C.Cir. 1981). The existence of confidentiality agreements binding employees not to reveal the information is another factor considered by the courts. Greenberg v. FDA, 803 F.2d at 1216-1218.

The courts have also been very clear in finding commercial development information covered by Exemption 4 where the release of such information could allow competitors to procure a clear understanding of a company's business practices and allow a competitor to cause harm to a company's competitive standing. See, e.g., Braintree Electric Light Dept. v. Dept. of Energy, 494 F.Supp. 287, 289-291 (D.D.C. 1980). Information on distribution channels, market strategies, pricing structures, and patterns of competition fall squarely within the Exemption because such information enables a competitor to gain an accurate picture of a company's marketing activities and the competitive structure of the market. Timken v. U.S. Customs Service, 531 F.Supp. 194, 200 (D.D.C. 1981). Typically, information concerning marketing strategies, and the names of independent contractors participating in a company's studies have been accorded confidential treatment. See, e.g., Teich v. Food & Drug Administration, 751 F. Supp. 243, 253 (D.D.C. 1990). Specific justifications for treating information in these two categories as CBI are provided below.[1]

GENE DESCRIPTION

The essence of the commercial value of the Monsanto biotechnology products is the particular genetic information that confers the desired properties on the plant product, as well as the technical know-how inherent in this information. Monsanto is at the leading edge in the development of biotechnology products in a rapidly growing and highly competitive industry. This expertise has been gained through many man years of effort, and the expenditure of tens of millions of dollars on biotechnology research.

Monsanto has been working on the development of marker genes in plants and their use in insect and virus resistant and herbicide tolerant crops since the early 1980's and has expended several million dollars in research and testing costs. Monsanto can document the development and testing costs by means of monthly summaries of the man hours devoted to these projects, budgetary documents, field test agreements, and project documents for the Chesterfield facility.

1 In a case recently decided by the U.S. Court of Appeals for the District of Columbia Circuit, Critical Mass Energy Project v. NRC, No. 90-5120, August 21, 1992, the court determined that information given to the government voluntarily will be treated as confidential under Exemption 4 if such information is of the kind that the provider would not customarily make available to the public. To the extent any references and other information in the Monsanto applications were submitted voluntarily, such information is accorded protection from disclosure.

OR120018_BR_011916

The uniqueness of Monsanto's products lies in the particular combination of genetic components in the vectors transferred to these plants. Each genetic entity in these vectors has three pieces of information: a promotor region, the gene for the expression of the trait, and a stop signal. Although the information on each of these vector components may be in the public domain, the particular combination of the components put together by Monsanto is unique and represents years of effort and millions of dollars of expense.

To achieve the products which are the subject of this Confidential Business Information Justification, Monsanto has developed and tested many different plant strains using different combinations of genetic components. The plant products developed by Monsanto represent the best fit of the components, and the best mode of gene expression of the desired traits. The specific combination of genetic information on the vectors transferred to the Monsanto products has been kept strictly confidential. Monsanto employees and contractors under contract to Monsanto are contractually obligated to keep this information confidential.

There are many competitors of Monsanto, both national and international, who have the expertise not only to replicate Monsanto's products, but also to use Monsanto's technology to develop other products which would be competitive with Monsanto, thereby saving millions of dollars and years of development effort. These competitors include companies such as Calgene, Rhone-Poulenc, Zeneca, and Ciba.

Monsanto's competitors cannot presently duplicate Monsanto's commercially valuable products from information in the public domain without going through the same painstaking trial and error development and testing of many different combinations of genetic information. It is important to emphasize that although there may be information about Monsanto products available in patent applications, this information is voluminous and general in nature, and does not identify the specific combinations of genetic information which Monsanto has found to be most effective. A competitor cannot determine from the patent applications which particular combination of genes and transgenic products will prove to be commercially valuable.

Access to gene description information for Monsanto's products would allow competitors to create essentially "copy-cat" products (avoiding any technical patent infringement) that would result in a market share loss for Monsanto of millions of dollars. By performing simple copy work, these competitors would avoid the millions of dollars and many years of research and development effort expended by Monsanto to develop its commercial products.

The release of gene description information would also provide competitors with commercially valuable knowledge about the particular products that Monsanto is planning to commercialize and the likely time frame for commercialization. This information would be extremely helpful to these companies in developing their own marketing strategies and development plans in a highly competitive market.

OR120018_BR_011917

NAMES AND INFORMATION ABOUT GENES, PROMOTERS AND EXPRESSED TRAITS

The release of information about the genes and promoters in the vectors will directly provide competitors with the knowledge of the precise genetic sequence - that Monsanto has found to be most desirable. If this information is disclosed, the competitors will have access to the structure of the Monsanto products, with the consequences outlined above. Patents for the products at issue in this matter are pending, but have not been issued.

Information on the expressed trait of the genes is tantamount to providing the name of the genes, and will allow Monsanto's competitors to readily identify the particular genes that have been transferred to the Monsanto products. The release of any information relating to changes made to an original gene to facilitate fusion with another gene would explicitly reveal Monsanto's trade secret technology for developing gene combinations.

IDENTITY AND CHARACTERISTICS OF DONOR ORGANISM

A donor organism is not claimed as CBI when the gene from such organism appears alone. CBI is only claimed for the name and/or identifying characteristics of a donor organism when the gene from this organism is used in a new and unique combination with another gene to give greatly enhanced expression of the desired trait.

The identity of the donor organisms for wheat has been claimed as confidential by Monsanto because the disclosure of this information will essentially reveal to Monsanto's competitors the nature of the genes for the expressed traits. Likewise, information on the characteristics of the donor organisms and the source of the characterization of the donor will reveal directly or with little difficulty the identify of the donor organism. With this information in hand, even without information on the other components of the vector, Monsanto's competitors will be accorded a tremendous advantage in their search for competitive products, and will be able to unfairly take advantage of the expensive and time intensive effort by Monsanto to identify this donor as the most suitable organism for providing the genetic information necessary to best express the desired traits.

Page	Category of Information	Justification
2	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
2	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
3	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms

OR120018_BR_011918

3	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
4	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
4	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
4	Identity of Donor Organism	See discussion on Identity and Characteristics of Donor Organisms
6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
6	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
7	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
8	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
10	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011919

11	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
11	Description of Gene	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.
12	Description of Promoter	See discussion on gene description - names and information about genes, promoters, and expressed traits.

OR120018_BR_011920

	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a.	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article	X	
b.	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics).	X	
c.	A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article.	X	
d.	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced.	X	
e.	A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design.	X	
f.	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product, and, regulated article.	X	
g.	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location; production, propagation, and manufacture location; proposed sale and distribution location).	X	
h.	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.	X	
i.	A detailed description of the proposed method of final disposition of the regulated article.	X	

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

OR120018_BR_011921

Monsanto 96-166-01R

Monsanto Company
700 Chesterfield Parkway North
St. Louis, Missouri 63198
Phone: (314) 694-1000

June 11, 1996

Ms. E. Dianne Hatmaker
Biotechnology, Biologics, and Environmental Protection
Biotechnology Permits
4700 River Road, Unit 147
Riverdale, MD 20737-1237

Subject: Request for Field Release Permit
Monsanto # 96-113PR

Dear Ms. Hatmaker:

Please find attached a permit request for the Release of a Regulated Organism, Wheat. This release will be conducted in the state of Arizona. In support of this request, please find a completed APHIS Form 2000 and supporting information for the vectors.

This release contains confidential business information (CBI) and is so marked. This confidential information was developed by Monsanto at its own expense, has not been released to anyone not under a secrecy agreement to Monsanto and has not been published. We request that this information not be released as it has value to our competitors (domestic and foreign) in that they would be able to copy this work and unfairly compete with us causing financial loss and other harm to Monsanto.

We appreciate your attention to this matter. Should you have any questions, please feel free to contact me at 314/537-7065.

Sincerely,

Ramona Edwards

Ramona G. Edwards
Administrative Assistant

OR120018_BR_011922

CBI DELETED

APHIS FORM 2000 ATTACHMENTS

This request for a Release into the Environment Permit is to allow the field testing of transgenic wheat which has been modified to be herbicide tolerant. All of the information required to support this permit is found in this application.

The plasmid vector constructs that will be a part of these field experiments are: PV-TXCT01, PV-TXCT15, PV-TXCT23 and PV-TXGT02.

Item 6. The following is the information required to identify the donor, recipient and regulated organisms and vector agent:

For the plasmid vector PV-TXCT01 (PV-TXGT01 + PV-TXSM01):

Plasmid Vector PV-TXGT01:

Name	Scientific Name	Common Name
a. Donor Organism	[*Arabidopsis thaliana* *Agrobacterium sp.* *Achromobacter* sp.	]
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector or Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid Vector PV-TXSM01:

Name	Scientific Name	Common Name
a. Donor Organism	[*Escherichia coli*	]
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

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CBI DELETED

b. For the plasmid vector PV-TXCT15 (PV-TXFR05 + PV-TXSM09)

Plasmid Vector PV-TXFR05:

Name	Scientific Name	Common Name
a. Donor Organism	[	]
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid Vector PV-TXSM09:

Name	Scientific Name	Common Name
a. Donor Organism	[*Agrobacterium sp.*	]
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

OR120018_BR_011924

CBI DELETED

c. For Construct PV-TXCT23 - (PV-TXSM09 + PV-TXSM12)

Plasmid Vector PV-TXSM09:

Name	Scientific Name	Common Name
a. Donor Organism	[*Agrobacterium sp.*]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

Plasmid Vector PV-TXSM12:

Name	Scientific Name	Common Name
a. Donor Organism	*Agrobacterium sp.* [ ]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

d. For Plasmid Vector PV-TXGT02

Name	Scientific Name	Common Name
a. Donor Organism	[*Arabidopsis thaliana* *Agrobacterium sp.*]	
b. Recipient Organism	*Triticum aestivum*	wheat
c. Vector of Vector Agent	particle gun	
d. Regulated Organism	*Triticum aestivum*	wheat

OR120018_BR_011925

Item 9. The donor, recipient and vector organisms were collected in the United States. The vector construct and transgenic wheat were developed by Monsanto at the Chesterfield Village Laboratories. The seed was generated from laboratory trials conducted at Monsanto Company.

Item 10. The location of the field experiment:

Yuma County, Arizona

(b) (4)

Item 13a. The transgenic wheat that is the subject of this permit request was developed by scientists at Monsanto.

Item 13b. All of the testing, to date, suggests that the modified plants are identical morphologically, structurally, physiologically, etc., to the non-modified parental variety.

Item 13c. The following is a detailed description of the molecular biology of the system used to produce the regulated article.

OR120018_BR_011926

CBI DELETED

Construct Descriptions for PV-TXCT01

PV-TXGT01 AND TXSM01 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXGT01

This construct is a free delivery: pUC-Kan vector containing 2 genes (the selectable markers) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CmoVa/[ ]** A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
CBI [

]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants. CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature CP4 protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI **CmoVa/[ ]** A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
CBI [

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OR120018_BR_011927

CBI DELETED

Constructs PV-TXCT01 (Cont'd)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.
CTP1-GMEsyn is a gene fusion composed of the N-terminal 0.26 Kb chloroplast transit peptide sequence derived from the *Arabidopsis thaliana* SSU 1a gene (CTP1) (Timko et al. 1988, The Impact of Chemistry on Biotechnology, ACS Books, 279-295), and the C-terminal 1.3 Kb synthetic gene sequence (GMEsyn). GMEsyn gene encodes the enzyme glyphosate oxidoreductase from an *Achromobacter* sp. strain LBAA which catalyzes the conversion of glyphosate to herbicidally inactive products, aminomethylphosphonate and glyoxylate. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature GMEsyn protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

Construct Description for PV-TXSM01

This construct is a free delivery: pUC-Kan vector containing 1 gene (the scorable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/[ ]** A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).
CBI **[**

]

GUS The expression of this gene is used as a scorable marker for plant transformation. GUS is a 1.8 Kb coding region of the ß-glucuronidase gene (Jefferson et al. 1986, Proc Natl Acad Sci USA 83: 8447-8451).

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011928

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT15

PV-TXFR05 AND PV-TXSM09 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXFR05

This construct is a free delivery: pUC-Kan vector containing one gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows the order of promoter, coding region, and 3' non-translated end.

CBI **CMP1/[ ]** The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.

CBI [

]

Antifungal Protein Gene II Expression of AFP2 confers resistance to fungal diseases.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

Construct Description for PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/[ ]** A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [

]

OR120018_BR_011929

Construct Description for PV-TXCT15 (Cont'd)

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants. CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature CP4 protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011930

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXCT23

PV-TXSM09 AND PV-TXSM12 were introduced into the same plant cell through a particle acceleration method. The result is that at a high frequency the plasmid molecules integrate into the genome of the plant cell. Generally the integration is into one chromosomal location in the plant cell. Less frequently, plasmids integrate into multiple chromosomal locations. In either case, there is integration of the genes into the same plant cell, and any plants produced from that cell.

Construct Description for PV-TXSM09

This construct is a free delivery: pUC-Kan vector containing 1 gene (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the gene in this construct follows. The order of the descriptions for the chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMoVa/[ ]** A caulimovirus promoter plus intron. More specifically, the 0.6 Kb 35S cauliflower mosaic virus (CaMV) promoter (Odell et al, 1985, Nature 313-810-812) with the duplicated enhancer region (Kay et al, 1987, Science 236:1299-1302).

CBI [

]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants. CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature CP4 protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011931

CBI DELETED

Construct Description for PV-TXCT23 (Cont'd)

Construct Description for PV-TXSM12

This construct is a free delivery: pUC-Amp vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **TSP3/[ ]** The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

CBI [

]

AS1 Expression of this sequence alters the expression of marker genes.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI **TSP3/[ ]** The TSP2 (Tissue-specific Promoter 3) plus intron is used to direct expression of foreign genes in plants.

CBI [

]

TMG1 The expression of this gene is used as a marker for plant transformation.

CBI [

]

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011932

CBI DELETED

CONSTRUCT DESCRIPTION FOR PV-TXGT02

This construct is a free delivery: pUC-Kan vector containing 2 genes (including the selectable marker) and is delivered to the recipient organism using the particle gun. The description of the genes in this construct follows. The order of the descriptions for each chimeric gene is promoter, coding region, and 3' non-translated end.

CBI **CMP1/[ ]** The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.
CBI [

]

CTP2-CP4 Expression of CTP2-CP4 confers glyphosate tolerance in plants. CTP2-CP4 is a gene fusion composed of the N-terminal 0.23 Kb chloroplast transit peptide sequence from the *Arabidopsis thaliana* EPSPS gene (CTP2) (Klee et al. 1987, Mol Gen Genet 210: 437-442), and the C-terminal 1.36 Kb 5-enolpyruvylshikimate-3-phosphate synthase gene (CP4) from an *Agrobacterium* species. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature CP4 protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

CBI **CMP1/[ ]** The CMP1 (Constitutive monocot promoter 1) is used to direct expression of foreign genes throughout all tissues in monocot plants.
CBI [

]

OR120018_BR_011933

Construct Description for PV-TXGT02 (Cont'd)

CTP1-GMEsyn Expression of CTP1-GMEsyn confers glyphosate tolerance in plants.
CTP1-GMEsyn is a gene fusion composed of the N-terminal 0.26 Kb chloroplast transit peptide sequence derived from the *Arabidopsis thaliana* SSU 1a gene (CTP1) (Timko et al. 1988, The Impact of Chemistry on Biotechnology, ACS Books, 279-295), and the C-terminal 1.3 Kb synthetic gene sequence (GMEsyn). GMEsyn gene encodes the enzyme glyphosate oxidoreductase which catalyzes the conversion of glyphosate to herbicidally inactive products, aminomethylphosphonate and glyoxylate. Plant expression of the gene fusion produces a pre-protein which is rapidly imported into chloroplasts where the CTP is cleaved and degraded (della-Cioppa et al. 1986, Proc Natl Acad Sci USA 83: 6873-6877) releasing the mature GMEsyn protein.

NOS 3' A 3' non-translated region (0.3 Kb) of the nopaline synthase gene (Fraley et al. 1983, Proc Natl Acad Sci USA 80: 4803-4807 and Depicker, et al. 1982, J. Molec Appl. Genet. 1:561-573) which functions to direct polyadenylation of the mRNA.

OR120018_BR_011934

FREE DELIVERY PARTICLE GUN (MONSANTO)

Introduction of DNA into plant tissue with the "biolistic" particle bombardment method has been described in detail by Klein et al. (1987, Nature 327: 70-73; 1988a, Bio/Technology 6: 559-563; and 1988b, Proc Natl Acad Sci USA 85: 4305-4309). The transgenic material in this application was produced using the commercially available particle delivery systems. Detailed instructions are available from the manufacturers. Briefly, DNA is precipitated onto microscopic (~1 μ diameter) tungsten or gold particles using calcium chloride and spermidine. A drop (2.5μl) of the coated particles is accelerated at a high velocity allowing the particles to penetrate the target plant cells, where the DNA is deposited and incorporated into the plant cell genome. The cells are incubated on a tissue culture medium which supports the growth of embryogenic callus. The introduced DNA contains a gene(s) encoding for resistance to either antibiotics (e.g., the NPTII gene for resistance to kanamycin and G418) or genes conferring herbicide resistance. The plant cells are grown in the presence of an appropriate antibiotic or herbicide, and only the transformed cells continue to grow. Plants are regenerated from the resistant embryogenic callus tissue, and are assayed for the presence of the introduced gene(s). The free delivery vectors are engineered to contain multiple chimeric plant expression genes in high copy E. coli plasmids.

OR120018_BR_011935

VECTOR DESCRIPTION FOR FREE DELIVERY: pUC-Kan

The free delivery vectors contain multiple chimeric plant expression genes engineered into pMON10081. The pMON10081 plasmid is a derivative of the high copy *E. coli* plasmid pUC119 (Viera and Messing 1987, Methods Enzymol 153: 3-11). It was constructed by fusing the 1.3 Kb FspI-DraI origin of replication fragment from pUC119, to the 1.3 Kb SmaI-HindIII (Klenow filled) fragment from pKC7 (Rao and Rogers 1979, Gene 7: 79). The pKC7 fragment contains the neomycin phosphotransferase type II gene which confers bacterial kanamycin resistance. The ß-lactamase gene conferring bacterial ampicillin resistance was completely deleted. Several chimeric plant expression genes can be introduced into pMON10081. These include the marker genes required for selection of the transformed plant tissue, and one or more chimeric genes of choice. The chimeric genes are engineered to contain the desired coding region fused between a promoter segment and a 3'-non-translated region. Integration of the vector into the plant chromosome results in the expression of the desired phenotype encoded by the chimeric genes.

OR120018_BR_011936

Item 13d. The plasmid vectors were constructed at the research laboratories of Monsanto Co. in St. Louis, Missouri. The initial wheat plants transformed with these vectors were also developed at the research laboratories of Monsanto Co. in St. Louis, Missouri, USA.

Item 13e. The information regarding the description of the proposed experiment for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design is found in the following protocol:

Purpose of the test:

The purpose is to evaluate the tolerance to Roundup® herbicide of the transgenic lines under field conditions, and to evaluate agronomic performance, yield and yield components of the lines.

Investigators:

Principle Investigator

Mr. Huaping Zhou
Monsanto Company/GG4H
700 Chesterfield Parkway North
St. Louis, MO 63198
314/537-6431
314/537-6950 (fax)

Site Investigator

(b) (4), (b) (6), (b) (7)(C)

(b) (4), (b) (6), (b) (7)(C) AZ (b) (4), (b) (6), (b) (7)(C)
(b) (4), (b) (6), (b) (7)(C)

Site Security:

This trials will be located on a privately owned farm. The owner has been instructed as to the nature of the experiment and the need to maintain these plants and seed separate from any other wheat not a part of this trial. Generally, the public is not allowed free access to public land, and the cooperator and owner will be instructed as to the need to frequently observe the plots for any signs of crop damage or vandalism.

OR120018_BR_011937

Agronomic Practices:

Ground preparation and fertility: ground preparation will follow normal practices for wheat. Fertilizer may be applied based on a soil test to bring the nutrient level up to that recommended for wheat. Additional fertilizer may be applied throughout the season as needed.

Weed control: Weed control will follow acceptable practices for wheat by using labelled herbicides, experimental herbicides, and/or hand weeding.

Disease control: Diseases may be controlled by the use of labelled fungicides for seed treatment and/or topical applications.

Insect control: Insect pests will be monitored for their appearance in the field. Insecticides labelled to control insect pests that are present may be applied as needed, including seed treatments or topical applications.

Isolation:

The experiment will be surrounded by a 20-foot border of wheat to prevent outcrossing to wheat or other species not a part of this trial.

Monitoring protocols of adequate duration are required to ensure that all volunteers resulting from the field testing of a genetically engineered crop are iddentified and eliminated.

Plot Design:

The experiment will be a randomized complete block with up to three replicates per treatment. The plots will be sprayed with 16 and 32 oz./A Roundup® at 2-4 and >5 leaf stages. The total area to be planted to the transgenic plants will be up to one acre.

Tentative Schedule:

Planting will be between October 15 1996 - December 15, 1996 depending on the weather and seed availability. Harvesting will be between April 1, 1997 - May 30, 1997 depending on weather and date of planting.

Harvest Procedures:

The plots will either be harvested by hand or with a small plot combine. If the combine is used, it will be thoroughly cleaned following completion of the plot harvesting and before leaving the plot area.

After harvesting, the test plots will be tilled to destroy the plant material. The plot area will be monitored for one year for surviving plants, which will be destroyed by hand, tillage or herbicide. Wheat or another small grain crop will not be planted in this area for one year.

OR120018_BR_011938

Item 13f. To avoid accidental mixing and loss, the shipping and maintenance of genetic engineered seeds and plants will include double containment, and devitalization of seeds and other material capable of propagation prior to disposal.

Item 13g. The wheat seed will be shipped to the location specified in item 10. Once received, the seed will be stored in a contained storage facility and used for field release. Any unused seed will be retained for later use or returned to Monsanto, St. Louis.

Item 13h. Once received, the seed will be stored in a locked storage facility and used for field release.

Item 13i. Any unused seed will be retained for later use or returned to Monsanto, St. Louis. For future use, the field will be planted to a crop other than wheat. Any wheat volunteer plants will be removed during the following season.

OR120018_BR_011939

This application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq. and the Plant Quarantine Act (7 U.S.C. 151 et seq.)). The information will be used to determine eligibility to receive all types of permits. No permit shall be issued until this application has been approved.

CBI DELETED

See reverse side for additional information.

FORM APPROVED
OMB NO. 0579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

(Genetically Engineered Organisms or Products)

96-113PR

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

1. NAME AND ADDRESS OF APPLICANT

(b) (6), (b) (7)(C)
Monsanto Company/BB3A
700 Chesterfield Parkway North
St. Louis, MO 63198

96-166-01R

2. PERMIT REQUESTED ("X" one)

- [ ] Limited - Interstate Movement
- [ ] Limited - Importation
- [X] Release into the Environment
- [ ] Courtesy Permit

3. THIS REQUEST IS *("X" one)*

- [X] New
- [ ] Renewal
- [ ] Supplemental

4. TELEPHONE NUMBER

(b) (6), (b) (7)(C)

5. MEANS OF MOVEMENT

- [ ] Mail
- [ ] Baggage or Handcarried
- [ ] Common Carrier
- By whom _____

6. GIVE THE FOLLOWING *(if applicable) (if more space is needed, attach additional sheet)*

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism:	See Attached			
b. Recipient Organism:				
c. Vector or Vector Agent:				
d. Regulated Organism or Product:				
e. If product, list names of constituents:				

7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS

NA

8. DATE *(or inclusive dates of period)* **OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE**

October 1, 1996 - September 30, 1997

9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

See Attached

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

See Attached

11. ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* **ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT**

None

12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

Not Applicable

13. SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON

(b) (6), (b) (7)(C)

15. PRINTED NAME AND TITLE

(b) (6), (b) (7)(C)

16. DATE

June 11, 1996

FOR APHIS USE ONLY

State Notification Sent	State Review Received	Permit Issued
July 29, 1996	August 13, 1996	[X] Yes [ ] No

Date of Determination	Permit No.	No. of Permit Labels Issued	Supplemental Conditions Enclosed
August 29, 1996	96-166-01r	n/a	[X] Yes [ ] No

Signature of BBEP Official	Date	Expiration Date
Arnold Foudin, Deputy Dir.	August 29 1996	August 29, 1996

DRE200138_BR_014940

APHIS FORM 2000 (JUL 89)

Replaces PPQ Form 1001 which may be used.

(continued on reverse)

	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a.	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article	X	
b.	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics)	X	
c.	A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article	X	
d.	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced	X	
e.	A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design.	X	
f.	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product, and, regulated article.	X	
g.	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location; production, propagation, and manufacture location; proposed sale and distribution location).	X	
h.	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.	X	
i.	A detailed description of the proposed method of final disposition of the regulated article.	X	

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

OR120018_BR_011941

Supplemental Permit Conditions

1. Biotechnology, Biologics, and Environmental Protection (BBEP) or a Regional Biotechnologist will conduct an inspection of the test site at the beginning of the test. The permittee is required to notify the State regulatory official, and the appropriate Regional Biotechnologist (see attached map) at least 1-week before the test begins.

2. Additional inspections may be conducted by the Regional Biotechnologist. The permittee is required to notify the Regional Biotechnologist and the State Official at least 1-week before termination of the experiment.

3. A field test data report must be submitted within 12 months after the permit issuance date. If a field test is still in progress at 12 months or any multiple of 12 months after the permit issuance date, additional field test data reports must be submitted to APHIS and State Official within subsequent 12 month periods. Final reports for those field tests lasting more than 12 months must be submitted to APHIS and State Official 6 months after the termination of the field test. Field test reports shall include: methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment. We encourage the inclusion of other types of data if the applicant anticipates submission of a petition for determination of non-regulated status for their regulated article. APHIS views these data reports as critical to our assessment of plant pest risk and development of regulatory policies based on the best scientific evidence. Failure by an applicant to provide data reports in a timely manner for a field trial may result in the withholding of permission by APHIS for future field trials.

Confidential Business Information (CBI) will be handled according to the APHIS policy statement at 50 FR 38561-63.

4. The test site shall be monitored for any volunteer plants after the completion of the test until the end of the following growing season for that crop in the area.

5. BBEP should be notified of any proposed changes to the protocol referenced in the permit application.

6. This approved Biotechnology Permit (APHIS form #2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (1) for the use of any non-genetically engineered plant pest or pathogens as challenge inoculum; (2) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (3) experimental use of unregistered chemical; and (4) food or feed use of genetically engineered crops harvested from the field experiment.

OR120018_BR_011942

Standard Permit Conditions
For the Introduction of a
Regulated Article
(7 CFR 340.3(f))

Permit Conditions: A person who is issued a permit and his/her employees or agents shall comply with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Deputy Administrator to be necessary to prevent the dissemination and establishment of plant pests:

(1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests.

(2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of plant pests.

(3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit.

(4) The regulated article shall be maintained only in areas and premises specified in the permit.

(5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article.

(6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation.

(7) The regulated article shall be subject to the application of measures determined by the Deputy Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article.

(8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the Deputy Administrator to be necessary to prevent spread of plant pests.

(9) A person who has been issued a permit shall submit to Biotechnology, Biologics, and Environmental Protection monitoring reports on the performance characteristics of the regulated article, in accordance with any monitoring reporting requirements that may be specified in a permit.

(10) Biotechnology, Biologics, and Environmental Protection shall be notified within the time periods and manner specified below, in the event of the following occurrences:

(i) Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article;

(ii) In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms);

(11) A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:

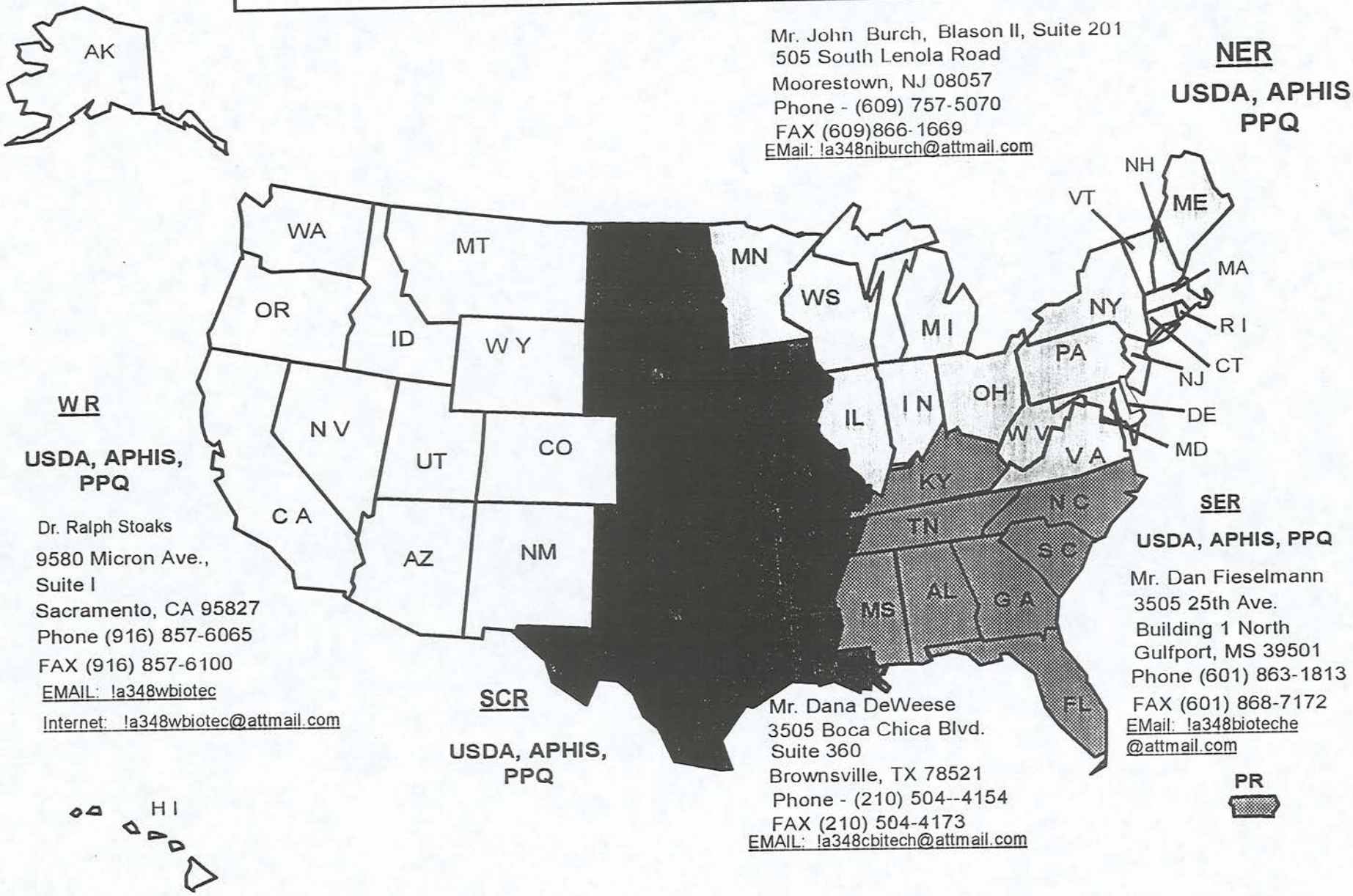
(i) Import or offer the regulated article for entry only at a port of entry which is designated by an asterisk in 7 CFR 319.37-14(b);

(ii) Notify Biotechnology, Biologics, and Environmental Protection promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

(iii) Mark and identify the regulated article in accordance with 7 CFR 340.5.

OR120018_BR_011943

PLANT PROTECTION AND QUARANTINE
Regional Contacts - (Biotechnology Activities)



WR

USDA, APHIS, PPQ

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EMail: !a348bioteche
@attmail.com

OR120018_BR_011944

	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a.	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article	X	
b.	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics)	X	
c.	A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article	X	
d.	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced	X	
e.	A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design.	X	
f.	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product, and, regulated article.	X	
g.	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location, production, propagation, and manufacture location; proposed sale and distribution location).	X	
h.	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.	X	
i.	A detailed description of the proposed method of final disposition of the regulated article.	X	

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

OR120018_BR_011945

FILE

29 AUG 1996

Ms. Ramona G. Edwards
Monsanto Agricultural Company/BB3A
700 Chesterfield Parkway North
St. Louis, MO 63198

Subject: Biotechnology Permit Number 96-166-01r to Conduct a Planned Release of Genetically Engineered *Wheat* Plants

The above permit has been approved after a Finding of No Significant Impact (FONSI) and a finding that the genetically engineered organisms do not present a risk of plant pest introduction or dissemination. You must adhere to the standard and supplemental conditions enclosed.

This permit should not be taken as any type of efficacy determination of the genetically engineered organisms.

Sincerely,

/s/ Arnold Foudin

Arnold S. Foudin, Ph.D.
Deputy Director
Biotechnology Permits

Enclosure:
Permit 96-166-01r
Supplemental Permit Conditions
Standard Permit Conditions
Map - Regional Biotechnologists

cc:
G. Thaxton, AZ Dept. of Agriculture, Phoenix, AZ
R. Stoaks, PPQ, Sacramento, CA
File 96-166-01r

BP:BBEP:APHIS:JWHITE:RAS:734-7612:8/29/96:I:\ISSUANCE\9616601R.IS

OR120018_BR_011946

This application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq. and the Plant Quarantine Act (7 U.S.C. 151 et seq.)). The information will be used to determine eligibility to receive all types of permits. No permit shall be issued until this application has been approved.

CBI: DELETED

See reverse side for additional information

FORM APPROVED OMB NO. 0579-0085

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION

APPLICATION FOR PERMIT OR COURTESY PERMIT UNDER 7 CFR 340

(Genetically Engineered Organisms or Products)

96-113PR

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

1. NAME AND ADDRESS OF APPLICANT

(b) (6), (b) (7)(C)

Monsanto Company/BB3A
700 Chesterfield Parkway North
St. Louis, MO 63198

96-166-01R

2. PERMIT REQUESTED ("X" one)

- [ ] Limited - Interstate Movement
- [ ] Limited - Importation
- [X] Release into the Environment
- [ ] Courtesy Permit

3. THIS REQUEST IS *("X" one)*

- [X] New
- [ ] Renewal
- [ ] Supplemental

4. TELEPHONE NUMBER

(b) (6), (b) (7)(C)

5. MEANS OF MOVEMENT

- [ ] Mail
- [ ] Baggage or Handcarried
- [ ] Common Carrier

By whom _____

6. GIVE THE FOLLOWING *(if applicable) (if more space is needed, attach additional sheet)*

	Scientific Name	Common Name	Trade Name	Other Designation
a. Donor Organism	See Attached			
b. Recipient Organism				
c. Vector or Vector Agent				
d. Regulated Organism or Product				
e. If product, list names of constituents				

7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS

NA

8. DATE *(or inclusive dates of period)* OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE

October 1, 1996 - September 30, 1997

9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE

See Attached

10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE

See Attached

11. ANY BIOLOGICAL MATERIAL *(e.g., culture medium, or host material)* ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT

None

12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE

Not Applicable

13. SEE REVERSE SIDE

I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

False Statement: Falsification of any item on this application may result in a fine of not more than $10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)

14. SIGNATURE OF RESPONSIBLE PERSON	15. PRINTED NAME AND TITLE	16. DATE
(b) (6), (b) (7)(C)	(b) (6), (b) (7)(C)	June 11, 1996

FOR APHIS USE ONLY

State Notification Sent	State Review Received	Permit Issued
July 29, 1996	August 13, 1996	[X] Yes [ ] No

Date of Determination	Permit No.	No. of Permit Labels Issued	Supplemental Conditions Enclosed
August 29, 1996	96-166-01r	n/a	[X] Yes [ ] No

Signature of BBEP Official	Date	Expiration Date
Arnold Foudin, Deputy Director, BP	August 29 1996	August 29, 1996

OR120018_BR_011947

APHIS FORM 2000 (JUL 89) *Replaces PPQ Form 1001 which may be used.*

(continued on reverse)

	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article	X	
b	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the non-modified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics)	X	
c	A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article	X	
d	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced	X	
e	A detailed description of the purpose for the introduction of the regulated article including a detailed description of the proposed experimental and/or production design.	X	
f	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and, regulated article.	X	
g	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location, production, propagation, and manufacture location; proposed sale and distribution location).	X	
h	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.	X	
i	A detailed description of the proposed method of final disposition of the regulated article.	X	

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

OR120018_BR_011948

Supplemental Permit Conditions

1. Biotechnology, Biologics, and Environmental Protection (BBEP) or a Regional Biotechnologist will conduct an inspection of the test site at the beginning of the test. The permittee is required to notify the State regulatory official, and the appropriate Regional Biotechnologist (see attached map) at least 1-week before the test begins.

2. Additional inspections may be conducted by the Regional Biotechnologist. The permittee is required to notify the Regional Biotechnologist and the State Official at least 1-week before termination of the experiment.

3. A field test data report must be submitted within 12 months after the permit issuance date. If a field test is still in progress at 12 months or any multiple of 12 months after the permit issuance date, additional field test data reports must be submitted to APHIS and State Official within subsequent 12 month periods. Final reports for those field tests lasting more than 12 months must be submitted to APHIS and State Official 6 months after the termination of the field test. Field test reports shall include: methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment. We encourage the inclusion of other types of data if the applicant anticipates submission of a petition for determination of non-regulated status for their regulated article. APHIS views these data reports as critical to our assessment of plant pest risk and development of regulatory policies based on the best scientific evidence. Failure by an applicant to provide data reports in a timely manner for a field trial may result in the withholding of permission by APHIS for future field trials.

Confidential Business Information (CBI) will be handled according to the APHIS policy statement at 50 FR 38561-63.

4. The test site shall be monitored for any volunteer plants after the completion of the test until the end of the following growing season for that crop in the area.

5. BBEP should be notified of any proposed changes to the protocol referenced in the permit application.

6. This approved Biotechnology Permit (APHIS form #2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (1) for the use of any non-genetically engineered plant pest or pathogens as challenge inoculum; (2) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (3) experimental use of unregistered chemical; and (4) food or feed use of genetically engineered crops harvested from the field experiment.

OR120018_BR_011949

Standard Permit Conditions
For the Introduction of a
Regulated Article
(7 CFR 340.3(f))

Permit Conditions: A person who is issued a permit and his/her employees or agents shall comply with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Deputy Administrator to be necessary to prevent the dissemination and establishment of plant pests:

(1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests.

(2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of plant pests.

(3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit.

(4) The regulated article shall be maintained only in areas and premises specified in the permit.

(5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article.

(6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation.

(7) The regulated article shall be subject to the application of measures determined by the Deputy Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article.

(8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the Deputy Administrator to be necessary to prevent spread of plant pests.

(9) A person who has been issued a permit shall submit to Biotechnology, Biologics, and Environmental Protection monitoring reports on the performance characteristics of the regulated article, in accordance with any monitoring reporting requirements that may be specified in a permit.

(10) Biotechnology, Biologics, and Environmental Protection shall be notified within the time periods and manner specified below, in the event of the following occurrences:

(i) Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article;

(ii) In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms);

(11) A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:

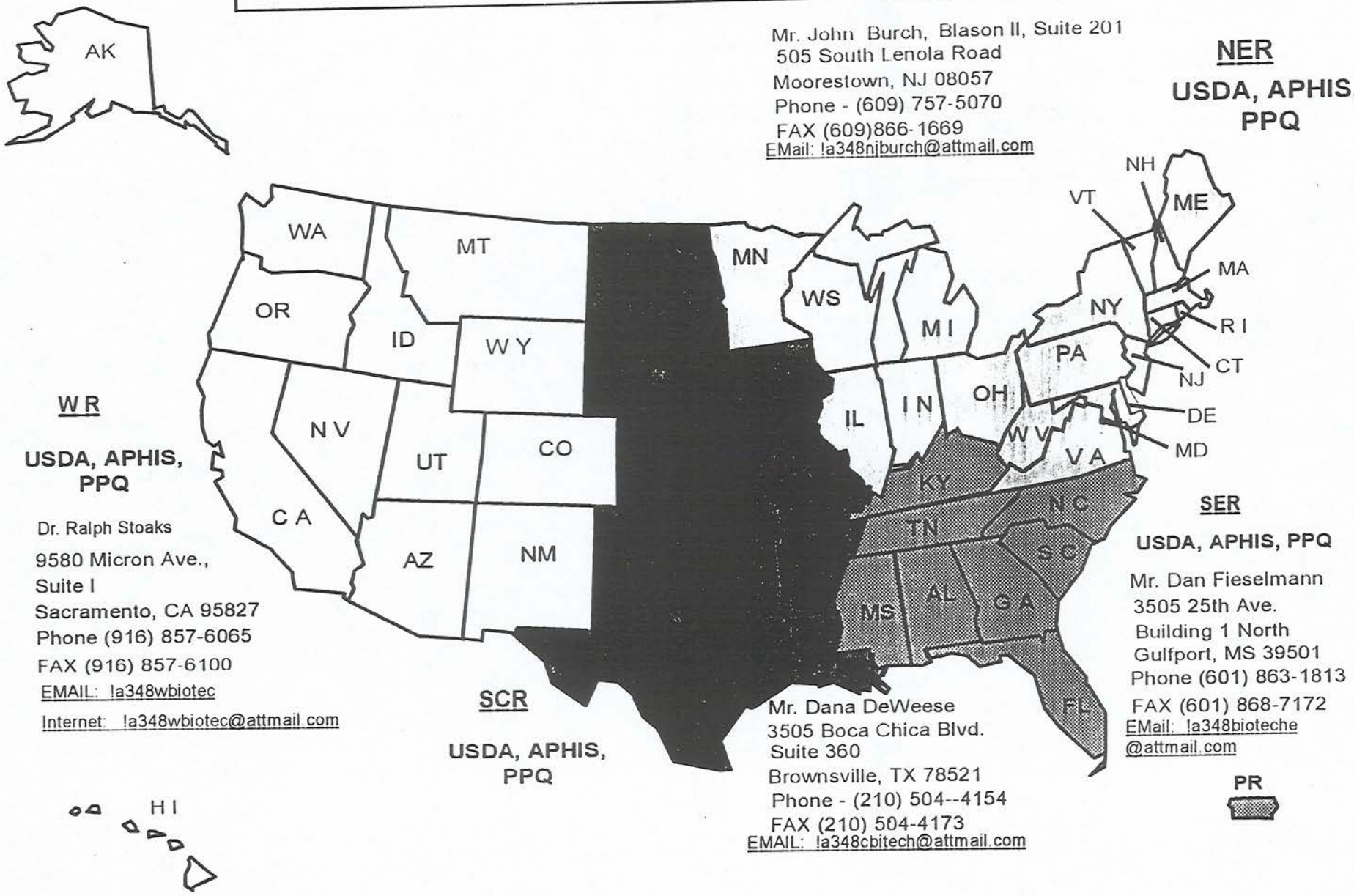
(i) Import or offer the regulated article for entry only at a port of entry which is designated by an asterisk in 7 CFR 319.37-14(b);

(ii) Notify Biotechnology, Biologics, and Environmental Protection promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and

(iii) Mark and identify the regulated article in accordance with 7 CFR 340.5.

OR120018_BR_011950

PLANT PROTECTION AND QUARANTINE
Regional Contacts - (Biotechnology Activities)



WR

USDA, APHIS, PPQ

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@attmail.com

OR120018_BR_011951

FILE COPY

APHIS APPLICATION NO. 96-166-01r
DATE: July 29, 1996

STATES'S RESPONSE TO APHIS' INITIAL REVIEW OF AN APPLICATION FOR THE INTRODUCTION OF A REGULATED ARTICLE UNDER 7 CFR 340

X State concurs with APHIS' initial review.

_____ State concurs with APHIS' initial review and offers the following comments (use additional sheets if necessary):

_____ State does not concur with APHIS' initial review and offers the following reasons for nonconcurrence (use additional sheets if necessary):

Name of State Official: Kenneth L. Boyd

Title: Associate Director

Agency or Department: Arizona Department of Agriculture

Address: 1688 West Adams

City, State, Zip Code: Phoenix, AZ 85007

Signature: (b) (6), (b) (7)(C)

Date: August 2, 1996

PLEASE RETURN THIS FORM WITHIN 30 DAYS OF THE DATE LISTED ABOVE TO:

James White
USDA, APHIS, BBEP
Biotechnology Permits
4700 River Road, Unit 147
Riverdale, MD 20737

RECEIVED

OR120018_BR_011952

FILE
96-166-01R

JUL 29 1996

Mr. Glen Thaxton, Assistant Director
Department of Agriculture
1688 West Adams
Phoenix, AZ 85007

Dear Mr. Thaxton:

This letter contains our review of an application submitted by Monsanto Agricultural Company of St. Louis, Missouri, for a permit that would allow the field testing of genetically engineered wheat. The field test is proposed for October 15, 1996 and will be conducted in Yuma County, Arizona.

This application was submitted pursuant to regulations found in 7 CFR Part 340, which regulate the introduction (importation, interstate movement, or release into the environment) of certain genetically engineered organisms and products which are regulated articles. The regulations, which were promulgated pursuant to authority granted by the Federal Plant Pest Act and Plant Quarantine Act, require that a person obtain a permit from the Animal and Plant Health Inspection Service (APHIS) prior to introducing a regulated article. This assessment serves to give notice to the State and to afford the State the opportunity to expressly indicate concurrence or nonconcurrence with APHIS' assessment. Please review the enclosed document and return acknowledgment, associated comments, or reasons for nonconcurrence (if applicable) to APHIS within 30 days from the date of this letter. Please use the enclosed form, and use additional sheets for response if needed.

For purposes of this submission, these genetically engineered wheat are deemed "regulated articles" (as defined in Section 340.1 of the regulations) because they contain DNA sequences that were derived from plant pests. Under the regulations, one basis for designating an organism as a regulated article is if it is genetically engineered (as defined in Section 340.1) from a donor organism, recipient organism, or vector or vector agent, which is listed in Section 340.2 of the regulations, and the listed organism is a plant pest (as defined in Section 340.1).

Pursuant to the procedures set forth in Section 340.3 of the regulations, we have prepared our findings in this letter for your notification and review. Enclosed is a nonconfidential set of documents prepared by Monsanto. It is very important that our office receive comments and opinions from State regulatory officials regarding the issuance of permits for the release of genetically engineered organisms into the environment. Since the researchers would like to conduct the field test starting in October 15, 1996, time is critical. Therefore, please forward your comments to me as soon as possible.

OR120018_BR_011953

Although the wheat are regulated articles because they contain DNA sequences that were derived from plant pests, we have concluded that the controlled field testing of these genetically engineered plants will not present any risk of plant pest introduction or dissemination for the reasons cited below.

1. Recipient-related Impacts. From the information provided with the application for permit, it appears that there is no risk of plant material escaping into or surviving in the ecosystem beyond the termination of the experiment. Neither is there a risk of any gene from these modified plants becoming mixed with the gene pool of any wheat population or any nontarget plant species outside of the experimental site. The transformed wheat plants have gained no apparent selective advantage over nontransformed plants with regard to their ability to become established in the ecosystem. Dissemination of pollen from engineered plant will be minimized a 20 foot border of nonengineered wheat which will act as a trap for pollen. Trap plants and their progeny will be disposed in a manner similar to the transgenic plants. These measures should be sufficient to minimize the escape of pollen from the transgenic wheat plants.

2. Donor-related Impacts. The purpose of this field trial is to evaluate the herbicide tolerance of the transgenic wheat. This wheat was modified by expressing the 5-enol pyruvylshikamate-3-phosphate synthase gene from *Agrobacterium* sp. and the glyphosate oxidase gene from *Achromobacter* sp. Expression of these genes in the wheat plant results in a plant that is tolerant to the herbicide glyphosate. Also, a marker gene, beta-glucuronidase, is also present in these transgenic plants.

The transgenic plants also contain noncoding DNA sequences, promoters and terminators, that were derived from organisms that are listed as plant pests. The function of these DNA sequences in the modified plants is to regulate expression of the introduced genes. The regulatory sequences cannot cause plant disease by themselves or in conjunction with the genes they regulate.

3. Vector Related Impacts. The introduced genes were transferred into wheat by particle gun bombardment of immature wheat embryos.

4. Quarantine of Organism and Final Disposition. The test site is expected to provide excellent physical security. Site monitoring and management practices that create a nonpropagative environment are expected to provide the necessary degree of both biological and physical containment. After harvesting, the test plots will be tilled to destroy the plant material. The plot area will be monitored for one year for surviving plants, which will be destroyed by hand, tillage, or herbicide application. Wheat or another small grain crop will not be planted on this site for one year.

OR120018_BR_011954

Staff Contact

If you have any questions about this application or our preliminary findings, please contact me at Area Code (301) 734-5940 or facsimile number (301) 734-8669. Please refer to permit application number 96-166-01r in your correspondence regarding this application. APHIS hopes to maintain its excellent working relationship with your State and encourages your participation and comments prior to issuance of the permit.

Sincerely,

/s/ (b) (6), (b) (7)(C)

James L. White, Ph.D.
Team Leader
Biotechnology Permits

2 Enclosures
Permit Application 96-166-01r
State Response Form

cc:
R. Stoaks, PPQ, Sacramento, CA
File 96-166-01r

APHIS:BBEP:BP:JW:hll:x7612:7/29/96:9616601.az